

- VOLUME 1 -

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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PAR PHARMACEUTICAL, INC. , : CIVIL ACTION  
 PAR STERILE PRODUCTS, LLC, :  
 and ENDO PAR INNOVATION :  
 COMPANY, :  
 Plaintiffs, :

vs. :

EAGLE PHARMACEUTICALS INC., :  
 Defendant. : NO. 18-823-CFC-JLH  
 (Consolidated)

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 PAR PHARMACEUTICAL, INC. , : CIVIL ACTION  
 PAR STERILE PRODUCTS, LLC, :  
 and ENDO PAR INNOVATION :  
 COMPANY, LLC, :  
 Plaintiffs, :

vs. :

AMNEAL PHARMACEUTICALS OF :  
 NEW YORK, LLC, et al. , :  
 Defendants. : NO. 18-2032-CFC-CJB

- - -

Wilmington, Delaware  
 Wednesday, July 7, 2021  
 8:30 o'clock, a.m.

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, Chief Judge

- - -

Valerie J. Gunning  
 Official Court Reporter

1 APPEARANCES:

2 FARNAN LLP

3 BY: MICHAEL E. FARNAN, ESQ.

4 -and-

5 DECHERT LLP

6 BY: MARTIN J. BLACK, ESQ.,

7 ROBERT RHOAD, ESQ.,

8 SHARON GAGLIARDI, ESQ.

(Philadelphia, Pennsylvania)

9 Counsel for Plaintiffs

10 Par Pharmaceutical, Inc., Par Sterile

11 Products, LLC, and Endo Par Innovation

12 Company, LLC

13 YOUNG, CONAWAY, STARGATT & TAYLOR, LLP

14 BY: ANNE SHEA GAZA, ESQ. and

15 SAMANTHA G. WILSON, ESQ.

16 -and-

17 GOODWIN PROCTER LLP

18 BY: HUIYA WU, ESQ.

19 (New York, New York)

20 Counsel for Defendants

21 Amneal Pharmaceuticals of New York, LLC,

22 et al.

23 POTTER ANDERSON & CORROON LLP

24 BY: DAVID E. MOORE, ESQ. and

25 BINDU A. PALAPURA, ESQ.

-and-

1       **APPEARANCES (Continued) :**

2  
3                   **KIRKLAND & ELLIS LLP**  
4                   **BY:   BRYAN S. HALES, ESQ.**  
5                   **(Chicago, Illinois)**

6                                   **-and-**

7                   **KIRKLAND & ELLIS LLP**  
8                   **BY:   JEANNA M. WACKER, ESQ. and**  
9                   **SAM KWON, ESQ.**  
10                   **(New York, New York)**

11                                   **Counsel for Defendant**  
12                                   **Eagle Pharmaceuticals Inc.**

13                                   **-   -   -**

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P R O C E E D I N G S

(Proceedings commenced in the courtroom,  
beginning at 8:30 a.m.)

THE COURT: Good morning. Please be seated.  
Folks in the courtroom -- let's do an IT thing before I  
start. My microphone is off. I know you all had to arrange  
for this foreign testimony. Do you know, was something done  
such that the microphones are on a different system?

MR. BLACK: It's working now, Your Honor.

THE COURT: Okay. So does anybody know what  
this microphone is for? Is this for the witness who is from  
Belgium?

TRIAL TECH: Yes, Your Honor.

THE COURT: So is it on all the time during  
trial? How does it work?

TRIAL TECH: It is on right now. We're going to  
be broadcasting over Zoom so the witness can hear.

THE COURT: Okay. And then just remind me. I  
guess as an outside counsel, who is on the receiving end of  
this microphone and the Zoom?

MS. WU: Just Dr. Winter.

THE COURT: Just Dr. Winter?

MS. WU: Just Dr. Winter.

1 THE COURT: Okay. Perfect. Somebody may want  
2 to check periodically to see if you can hear me. That's  
3 fine.

4 And then for members of the audience, I follow  
5 the CDC. There's no requirement that you wear a mask if you  
6 are vaccinated, but you should feel welcome to wear a mask  
7 if it makes you more comfortable. I do require any witness  
8 to testify without a mask for credibility findings.

9 All right. Mr. Farnan?

10 MR. FARNAN: Good morning, Your Honor. Michael  
11 Farnan for the plaintiff. With me are Martin Black, Sharon  
12 Gagliardi, Robert Rhoad and Jonathan Loeb, and also from  
13 Endo we have Guy Donatiello and from Par we have Larry  
14 Brown.

15 THE COURT: All right. Thank you very much.  
16 Ms. Gaza?

17 MS. GAZA: Good morning, Your Honor. Anne Gaza  
18 from Young Conaway on behalf of Amneal Pharmaceuticals.

19 I'm joined today, Your Honor, by Huiya Wu from  
20 Goodwin Procter, John Bennett also from Goodwin Procter, and  
21 Shaobo Zhu from Goodwin Procter, and my colleague, Samantha  
22 Wilson, as well as Brian Sommese, Senior Director of IP  
23 Litigation at Amneal.

24 THE COURT: Thank you. Mr. Moore?

25 MR. MOORE: Good morning Your Honor. David

1 Moore Potter Anderson on behalf of Eagle.

2 With me today from Kirkland & Ellis are Bryan  
3 Hales, Jeanna Wacker and Ben Lasky. We also have with us  
4 from Eagle, Scott Tariff and Dan O'Connor.

5 THE COURT: All right. Welcome. All right.  
6 Plaintiff?

7 MR. BLACK: Thank you, Your Honor. Before we  
8 get started, two housekeeping matters.

9 First of all, with respect to deposition clips,  
10 I think we resolved all the issues where clips would have to  
11 be played today, but for clips that are going to be played  
12 tomorrow, my understanding is that defense plans to play  
13 quite a few. There are objections and we need to know when  
14 Your Honor would like to hear those objections.

15 THE COURT: Probably during lunchtime. Yes.

16 MR. BLACK: That makes sense, Your Honor.

17 The second point is with respect to objections  
18 to opening statement slides. There are two issues with the  
19 defense slides. One I want to point out.

20 They are referring to a lot of original  
21 Vasopressin, which is the prior art product 4,883,48 --  
22 I'm sorry, 788435. They have almost no disclosures with  
23 respect to that in their expert report. It has become kind  
24 of their lead prior art reference. It's in a slide in the  
25 opening.

1                   Of course, anybody can stand up in an opening  
2                   and say I intend to prove this and not prove it later, but I  
3                   don't want the moment to pass because they are going way  
4                   beyond the bounds of what's in the report and I want to flag  
5                   that for now and give defense an opportunity to back off if  
6                   they intend to.

7                   THE COURT: All right. And so you don't need to  
8                   stand up during the opening as well.

9                   MR. BLACK: I think the slide is objectionable.

10                  THE COURT: Oh.

11                  MR. BLACK: I mean, it's a problem. If you said  
12                  something, he puts up a slide and it's an image of a  
13                  document. The document they can get into evidence but the  
14                  witness can't actually say anything about the document  
15                  because he didn't refer to it in his report, so anything  
16                  that the defense says about it will not be proved in the  
17                  case.

18                  THE COURT: Okay.

19                  MR. BLACK: So I'm just putting a marker down on  
20                  that.

21                  THE COURT: That's fine.

22                  MR. BLACK: The second problem is --

23                  THE COURT: And if you want to stand up when  
24                  that slide shows up, say objection. Don't say anything  
25                  else. I will remember.

1 MR. BLACK: Thank you, Your Honor. I really  
2 don't want to object in opening.

3 THE COURT: I figured as much. I'm not sure I  
4 will remember it.

5 MR. BLACK: Correct. I will make the record.

6 The second thing is they've done something  
7 rather unusual with their opening slides, which is because  
8 they are presenting people by deposition, they've taken  
9 pictures and put questions and answers into the -- a large  
10 number of them into the slides. I've never seen that  
11 before. That doesn't mean it's wrong.

12 THE COURT: I've seen tons of it.

13 MR. BLACK: Okay. We do have one specific  
14 objection to a question and answer from Dr. Kenesky, who was  
15 the prosecuting attorney in this case, who they are accusing  
16 of inequitable conduct.

17 He's an associate at Wilson Sonsini, and we have  
18 a question that's objected to and which we need to have the  
19 objection raised and resolved, and they can't --

20 THE COURT: All right. Before you go on, can  
21 you all please turn your phones off, because whoever's phone  
22 just went off, please silence all phones. You are not  
23 supposed to have them in there and the Marshals will escort  
24 anybody whose phone goes off during the trial out of the  
25 courtroom without any warning, so thank you.



1                   Sorry about that, Mr. Black.

2                   MR. BLACK: My apologies, Your Honor.

3                   THE COURT: It's not your fault. It's whoever's  
4 phone went off.

5                   MR. BLACK: So the issue they've got a slide  
6 from Dr. Kenesky here with testimony quoted which we object  
7 to and we have not had the objection resolved.

8                   THE COURT: What's the nature of the objection?

9                   MR. BLACK: The nature of the objection is that  
10 the question, the question was effectively, did you during  
11 the '239 patent prosecution in fact know that Mr. Kenney and  
12 Mr. Kannan, the inventors, did not invent something?

13                   And there was an objection that it assumes facts  
14 not in evidence and it calls for privileged communication.  
15 And then his answer was, I do not recall.

16                   It doesn't prove anything, but without the  
17 objection in between, it's an objectionable question, and  
18 without the objection in between for context, it should be  
19 omitted, and that objection has not been resolved yet and  
20 it's in an opening slide. That's the problem.

21                   THE COURT: Okay. Mr. Hales?

22                   MR. HALES: Yes. Briefly, Your Honor, what  
23 Mr. Black left out on this particular issue is that the  
24 question is did you know, this is to the prosecuting  
25 attorney -- did you know, or did you during the '239 patent

1 prosecution in fact know that Mr. Kenney and Mr. Kannan, who  
2 were the named inventors, did not invent the subject matter  
3 of the FDA label relied upon in the objection by the  
4 Examiner, but withheld it from the Patent Office?

5 The objection that they identified assumes  
6 facts. I don't think there's any valid question about what  
7 he did or didn't know. And then it says, it does implicate  
8 a communication with a client, so to the extent there's any  
9 nonprivileged information that you can share that's  
10 responsive to that question, feel free. That was the  
11 counsel's instruction to the witness. And the witness  
12 answered, I do not recall.

13 THE COURT: All right.

14 MR. HALES: I don't see the controversy on that.

15 THE COURT: We'll let it play. We can resolve  
16 it later. Yes?

17 MS. WACKER: Your Honor, with respect to the  
18 788345, we think it was properly disclosed. Do you want to  
19 hear argument about that before opening starts or would you  
20 rather deal with it when the witness is going to be  
21 testifying?

22 THE COURT: When the witness is going to be  
23 testifying.

24 MS. WACKER: Thank you.

25 THE COURT: All right. Oh, hold on.

1 MR. BLACK: May we approach, Your Honor?

2 THE COURT: Please.

3 (Binders handed to the Court.)

4 THE COURT: I want to compliment the parties on  
5 the pretrial order. I thought they were well written.

6 MR. BLACK: Thank you, Your Honor. Okay. The  
7 last time I had pressed a button up here, we had the screen  
8 crash, so I think we're okay now.

9 THE COURT: All right.

10 MR. HALES: Your Honor, while Mr. Black is  
11 getting ready, may we have some transition to get the boards  
12 for opening statements or would you rather get that done  
13 ahead of time?

14 THE COURT: You'll have time.

15 (Pause.)

16 THE COURT: Whenever you're ready.

17 MR. BLACK: Just waiting for the projector.

18 THE COURT: That's good. I'm trying to get up  
19 my realtime.

20 MR. BLACK: If this doesn't go in 30 seconds, I  
21 will just work off the screen.

22 THE COURT: Well, is this a court person?

23 TRIAL TECH: I'm with the tech company.

24 THE COURT: The tech company. It is your time,  
25 so however you want to do it.

1 MR. BLACK: Okay.

2 THE COURT: All right. Here we go.

3 MR. BLACK: There we go.

4 THE COURT: You just have to put a little  
5 pressure on people.

6 MR. BLACK: That will work. Your Honor, .

7 I'm pleased to finally open this case for my  
8 client, Par Pharmaceuticals and related companies.

9 Par is a pharmaceutical company that was  
10 originally based in Chestnut Ridge, New York. It is  
11 currently a subsidiary of Endo Pharmaceuticals, which is  
12 based in Malvern, Pennsylvania.

13 The branded product at issue in this case is  
14 Par's Vasostrict product. It comes in two versions -- a  
15 single dose vial with one millimeter and a multidose vial  
16 with ten milliliters. Both Eagle and Amneal have proposed  
17 to make generic versions of the single dose vial and Amneal  
18 also proposes to make a version of the multidose vial.

19 Vasostrict has an active ingredient called  
20 vasopressin. It is a vasoconstrictor that constricts blood  
21 vessels and causes blood pressure to rise. That's important  
22 in emergency situations where you have hypotension of the  
23 patient, particularly in shock. Blood pressure can drop  
24 precipitously and you need a drug which will very quickly  
25 raise the blood pressure. Vasopressin has been in use for

1       that for almost 100 years.

2               The shelf life of the drug today of Vasostrict  
3       product is 24 months refrigerated, stable for that length of  
4       time. It can also be refrigerated for 24 months and kept  
5       out at room temperature at 12 months and also remain  
6       remarkably stable.

7               The product is used primarily in hospitals and  
8       it's used in the following fashion -- syringes are used to  
9       puncture the cap of the vial. The solution is withdrawn and  
10      then injected into an IV bag, which is then infused into the  
11      patient. As I said, this is used primarily in emergency  
12      situations. There are other situations where low blood  
13      pressure is a problem. Obviously, too much of the drug,  
14      especially a powerful drug like this, would raise blood  
15      pressure, which can be quite dangerous with a patient, so  
16      it's carefully administered by doctors.

17              The drug itself originally called Pitressin was  
18      launched before 1920, and the FDA Act, which regulates drugs  
19      and really didn't come into force until 1938, and then, of  
20      course, the rules have changed since then. But as a result  
21      of that, the original version of vasopressin was not an  
22      approved product and there were versions of the product on  
23      the market, but there was very little known about the  
24      stability of the product, what the impurities were, and  
25      people were simply not paying attention to it because it was

1 an old product.

2 In the early 2010s, Par decided to begin a  
3 project to do research and development on this old drug and  
4 see if it could come up with something better and take the  
5 product to the through the full FDA process, the full rigors  
6 of 21st Century medicine, and they did that, they submitted  
7 the ANDA -- excuse me, the NDA in September of 2012, and it  
8 took them about two years and they got an approval, and then  
9 they kept innovating during this process.

10 So they were learning things about the drug that  
11 weren't known, about impurities, about stability, and they  
12 continued to innovate and brought out the second version of  
13 the product in 2016.

14 Now, during this case we're going to refer to  
15 the first version as original Vasostrict and the second  
16 version, which is being sold today, as reformulated  
17 Vasostrict. Sometimes someone might slip into calling it  
18 Vaso I or Vaso II, but that's the nomenclature we'll use at  
19 trial.

20 In August and September of 2017, the two  
21 asserted patents in this case issued, the '785 and the '209.  
22 Eagle and AMRI then filed an ANDA against the NDA that had  
23 been approved for Vasostrict. They originally filed against  
24 the first version of the product, which has been withdrawn  
25 from the market after a little over a year of sale, but what

1 happened is the FDA wanted additional data from them because  
2 they had to compare their product to the -- to the improved  
3 product, and so almost all of the data in their ANDA  
4 relating to stability and comparison to the drug product  
5 that has been approved comes from the new version of  
6 Vasostrict.

7 Amneal filed an ANDA and they filed against the  
8 reformulated version. As Your Honor knows, neither company  
9 has obtained approval yet.

10 So the patented inventions. We have two  
11 patents. They are both entitled Vasopressin Formulations  
12 For Use in the Treatment of Hypotension. The patent  
13 describes several embodiments of pharmaceutical formulations  
14 that provide advantages in stability, administration and  
15 efficacy. We're going to be addressing stability at great  
16 length in this case.

17 What is stability? Stability is an issue that  
18 arises in a drug product that degrades, particularly a  
19 peptide like vasopressin, which degrades in solution. What  
20 we show here on the slide is just a basic cartoon of the  
21 process. First you have API synthesis.

22 API is an active pharmaceutical ingredient, and  
23 we'll take care to make sure we identify any abbreviation,  
24 acronyms in this case as best we can. We tend to do that in  
25 these ANDA cases and I know it can be a problem.

1           API is active pharmaceutical ingredient that can  
2 be synthesized. It needs to be stored and then finished in  
3 the factory, shipped, stored and administered to patients.

4           In this case, Eagle's API is made outside the  
5 company. It's stored, it's shipped to a factory in New  
6 Mexico and made by a company called AMRI, which we'll  
7 hear about during the case, and then it will be shipped if  
8 it ever is approved to -- around the country to folks who  
9 need it or to Eagle for storage and then onward for sales  
10 elsewhere.

11           There's a relationship between impurities and  
12 potency. So as a drug degrades, the potency of the drug  
13 goes down. It may start with a potency of 100 or 98 or 102.  
14 They call that the assay, and a drug with a potency of an  
15 assay of 100 over time, that will go down, 99, 98, 97, and  
16 the rate of reduction is, the rate of reduction of potency  
17 of the assay.

18           Now, this case is going to be about the converse  
19 of that. As the drug is, potency is going down, the  
20 impurities are rising and these impurities can be dangerous.  
21 They can be immunogenic. People have immune reactions to  
22 the biologic drugs and their impurities, and because there  
23 are a large number of impurities, they have to be  
24 characterized and they need to be shown to be safe, which is  
25 the reason why both defendants are having -- have not had



1 approval yet. There are impurities in their product which  
2 need to be dealt with by the FDA before they can be  
3 approved, because they now can undergo as we did 21st  
4 Century review.

5 The active ingredient as I said is vasopressin.  
6 More specifically, it is synthetic arginine Vasopressin.  
7 This is the synthetic formula. What it shows is the yellow  
8 ovals are amino acids. This is a string of amino acids, the  
9 basic building blocks of life. There are about 20 amino  
10 acids which cover every protein in the body. These  
11 molecules are aqueous in aqueous solution and they do  
12 degrade.

13 Now, what happens is just one degradation  
14 pathway. We're not going to go through all of them. There  
15 are many, many of them, but what happens is, for instance,  
16 on the left-hand side, there's an H<sub>2</sub>N group. That can  
17 cleave off over time and the molecule would be exactly the  
18 same except the H<sub>2</sub>N group is gone. That molecule would then  
19 be known as gly9. If one of the other cleavage sites is  
20 where the NH<sub>2</sub> falls off, then it turns into a different  
21 impurity and it's impossible to predict without doing the  
22 research which impurities are going to arise and in what  
23 quantity.

24 Now, one of the things that Par did -- it was  
25 actually a company called JHP, so if you are JHP, that's

1 part of Par today. What they did is they were the first to  
2 characterize these impurities. They did the research. The  
3 drug had been around for 100 years. Nobody paid any  
4 attention to what the impurities were. They did the work to  
5 figure that out, and this is Figure 6 from both patents,  
6 which is an HPLC graph showing each spike is a different  
7 impurity.

8 And on the graph it shows SEQ ID and then it has  
9 various numbers. Each one of those SEQ IDs is a different  
10 impurity and they have a name and they are named in the  
11 patent in one of the tables and they're also named in the  
12 dependent claims. And infringement requires showing that  
13 these impurities are present in specific amounts, and  
14 invalidity conversely would require showing that the  
15 impurities are present in those amounts in any prior art  
16 product.

17 The other concept that we want to discuss with  
18 regard -- we're going to hear a lot about today is pH. I  
19 know Your Honor has some familiarity with it. Basically,  
20 water molecules. You add a proton. It becomes H<sub>3</sub>O, and the  
21 concentration of H<sub>3</sub>O, hydronium atom, is used to measure pH  
22 and that's used to measure acid and bases in everything from  
23 pharmaceuticals to swimming pools.

24 Now, during the research and development project  
25 and actually after the original product had been, had been

1 approved, there was work going on at Par to figure out if  
2 they could improve the product, and they did several studies  
3 on the pH of the product, trying out different ways to  
4 improve it. And what they learned during the course of the  
5 product development efforts was that the ideal range for the  
6 pH was 3.7 to 3.9, a very narrow band. The prior art taught  
7 a wide range of 2.5 to 4.5 in numerous references, which, of  
8 course, includes 2.5, 3.0, 3.5, and all the numbers in  
9 between. And when they filed for a patent, the patentee had  
10 to show that that range was critical over the range, which  
11 they were able to do and they got the patent.

12 So the invention here is a combination of pH at  
13 3.7 and 3.9 in a narrow range and a specific level of  
14 impurities.

15 The impurities are named in the form of SEQ IDs,  
16 which I will discuss in a moment. But just so we walk  
17 through one claim in the '785, this is the simplest claim.  
18 It's the product claim. The '209 has similar claims. They  
19 are method claims, so they discuss administering the  
20 product.

21 So the claim is a pharmaceutical composition  
22 comprising, in a unit dosage form, from about, and it has  
23 the dosage, and it's not disputed that that is present in  
24 the accused Eagle products.

25 The impurities limitation is wherein the unit

1 dosage form further comprises impurities that are present in  
2 an amount from .9 percent to 1.7 percent, wherein the  
3 impurities have from about 85 to about 100 percent sequence  
4 homology to SEQ ID Number 1. That's a mouthful. Let me  
5 just unpack that.

6 SEQ ID Number 1 is vasopressin. That's the  
7 active ingredient. Sequence homology means how close to  
8 vasopressin is the impurity, an impurity that's changed by  
9 one thing. It's going to have something less than  
10 100 percent, and an impurity that is then changed again and  
11 again and again will fall out below the 85 percent range.  
12 So what this is saying is you need a specific percentage of  
13 impurities that are very similar to vasopressin. Once you  
14 get beyond very similar, using broad terms here, the product  
15 is unlikely to work, could be unsafe. So that's the golden  
16 range.

17 The '209 patent incorporates those same concepts  
18 into a method of treatment. Now, the method of raising  
19 blood pressure with vasopressin we fully admit was known for  
20 a hundred years. These other elements, the concentration  
21 and administering it and the amounts to be administered to  
22 the patient and the hypotensive, they are all in the prior  
23 art and have been for decades.

24 Now, the dependent claims are in a slightly  
25 different form. They say with respect to the pharmaceutical

1 composition of claim 1, in other words, where you have .9 to  
2 1.7 percent of those type of impurities, you must have a  
3 specific amount of SEQ ID 4. 2 to .4 percent.

4 What is SEQ ID 4? Well, that's defined in Table  
5 1 in the patent. And what we see here is the circle, the  
6 circled composition is original vasopressin and then the  
7 patentee has discovered and listed these impurities in the  
8 table, and the ones that are going to be addressed in the  
9 case are impurities 2, 3, 4, 7 and 10, and they are given a  
10 SEQ ID. That is the -- the sequence is the amino acid  
11 sequence, and if the amino acid changes, the letter changes,  
12 and Dr. Kirsch, our expert, will be explaining some of that  
13 to the Court.

14 Now, that's the patent. Now let's discuss  
15 infringement. So we have one infringing product in this  
16 case. It's Eagle's ANDA 211538. As I said, it's a one  
17 millimeter single dose vial. It has the same active  
18 ingredient, the same proposed use and method of  
19 administration as Vasostrict, and they've conceded that all  
20 the impurity limitations are met and the case is therefore  
21 narrowed to the pH issue.

22 The claims at issue were for '785. Direct and  
23 indirect infringement are 1, 5 and 8. And for the '209, 1,  
24 4, 5 and 7. Because it's a method claim, the actual direct  
25 infringers are doctors who administer the drug and Eagle

1 induces.

2 I'm also listing the Amneal claims, but only  
3 because they will be challenged, we have a later trial,  
4 because of the infringement.

5 All right. So there are a couple of aspects  
6 about this case which are, which on the law, which I want to  
7 review. We did put it in the pretrial order, so I will be  
8 brief, but they are actually critical points and actually  
9 are dispositive of infringement in our view.

10 So one way to think about Hatch-Waxman  
11 infringement, is it's a conflict between two Article II  
12 decisions by the federal government.

13 On the one hand, the PTO grants a patent claim  
14 that grants the patentholder an exclusive right to practice  
15 the invention, and that's often seen in the form of a  
16 circle, which we have here on the right.

17 On the other hand, the FDA can grant a  
18 pharmaceutical company the right to make a product. And  
19 what happens if those two circles of authority granted by  
20 the federal government overlap? Well, we have infringement,  
21 and if we have a dispute about infringement, then we need an  
22 Article III Court to decide it.

23 Now, there are three principles that are going  
24 to be very important here. The first is that infringement  
25 is evaluated based on what the ANDA filer has asked the FDA

1 to approve. This is from the Sunovion case, and it says  
2 that what the generic manufacturer has asked the FDA to  
3 approve as a regulatory matter is the subject matter that  
4 determines whether infringement will occur. The generic is  
5 liable for infringement if it has asked the FDA to approve,  
6 and hopes to receive from the FDA approval to market a  
7 product within the scope of the issued claims.

8 Now, that's really important because it's what  
9 they put on paper. It's not what they tell the Court they  
10 are going to make. It's not about promises, whether they  
11 are made on the witness stand or from this podium right  
12 here. They are asking for approval, and if the approval is  
13 granted, they are entitled by law to use the full scope of  
14 that approval. So we have to litigate the full scope of the  
15 approval. This is not the first case to address this issue.  
16 The Federal Circuit has made very clear that there are no  
17 promises accepted in ANDA cases.

18 Also in the Sunovion case the Federal Circuit  
19 said that we therefore hold that any so-called certification  
20 pledging -- an attempt to file a certification with the  
21 Court saying even though our ANDA says X, we won't do it,  
22 unacceptable.

23 Any certification pledging not to infringe  
24 cannot override the conclusion that when a drug manufacturer  
25 seeks FDA approval to market a generic compound within the

1 scope of a valid patent, it is an infringement as a matter  
2 of law. Simply saying, "but I won't do it" is not enough to  
3 avoid infringement. No pinky promises in ANDA cases. What  
4 matters is what is the ANDA.

5 THE COURT: Which is 3.4 to 3.6.

6 MR. BLACK: Correct, Your Honor. And 3.4 to 3.6  
7 rounded, which is undisputed, which means Eagle, 3.6 means  
8 3.64, which is my next point.

9 Infringement is evaluated throughout the product  
10 life. A patent, a generic can't make a product, know that  
11 the day after it manufactures it, it's going to float into  
12 the infringing range and escape infringement, because that  
13 product will infringe.

14 And the Federal Circuit has addressed this issue  
15 as well, saying that infringement has to be evaluated  
16 throughout product life, and it's no excuse for the generic  
17 to say that, well, our ANDA says that it will float because  
18 you have to address infringement throughout product life and  
19 the fact that it escapes the Eagle factory barely within the  
20 range but then moves up into the infringing range during the  
21 course of its life is sufficient to prove infringement.

22 And that issue was addressed in Tyco where the  
23 Court said, it is not unreasonable for a patent owner to  
24 allege infringement under Section 271(e) (2) (A) if the patent  
25 owner has evidence that the as-marketed commercial ANDA



1 product will infringe even though the hypothetical product  
2 specified in the ANDA could not infringe.

3 So in this case, how do these principles come  
4 together? Well, Eagle is asking for approval --

5 THE COURT: You recognize there's tension  
6 between the two principles?

7 MR. BLACK: Yes, I do, Your Honor. What has to  
8 happen, Your Honor, you have to look at the ANDA and you  
9 have to look at what's going to happen -- you have to look  
10 at what the product that the ANDA holder is seeking approval  
11 will do. And in this case, what they have asked for is the  
12 right to make a product that goes right up to the line of  
13 where our patent rights are, and that's the interesting  
14 aspect of this case.

15 They are asking for permission to make a product  
16 with an upper bounded release of 3.6 rounded, which is 3.64.  
17 We have patent rights that begin at pH 3.7 to 3.9, which is  
18 3.65 rounded, and therefore they have to control their pH to  
19 within a hundredth of a pH value if they want to avoid  
20 infringement, or they always have the choice.

21 They had the choice until today to change the  
22 blue circle. The yellow circle stays. We can't change  
23 that. The Patent Office has said what our rights are.  
24 The blue circle, they can change, that and if they really  
25 believe that they can make the a product reliably and say

1 3.50 as they are going to say during the course of the case,  
2 they need to tell the FDA that they amend the application  
3 and then we wouldn't have a case. We wouldn't have a  
4 dispute.

5 But --

6 THE COURT: Well, wait. I just want to make  
7 sure. Is it your position they told the FDA they are going  
8 to make the product, in other words, the release is going to  
9 be 3.4 to 3.6, or are you saying they're representing in the  
10 ANDA that throughout the shelf life, which I think is  
11 through the expiry period, that this product is going to  
12 have a pH of 3.4 to 3.46?

13 MR. BLACK: They are asking the FDA to make a --  
14 to release the product at 3.6, 3.64.

15 THE COURT: They are asking the FDA to release.  
16 You are saying 3.6 is the release?

17 MR. BLACK: Yes. I'm sorry. I haven't really  
18 gone through that in detail. So there are different  
19 specifications.

20 THE COURT: Right.

21 MR. BLACK: There's an in-process specification,  
22 which is something they use during the course of manufacture  
23 to try to guide when making the product.

24 The key, the key specification is the release  
25 specification.

1 THE COURT: Right. Do you think it's  
2 undisputed -- first of all, you share the same definition of  
3 a release specification?

4 MR. BLACK: I believe so.

5 THE COURT: And the same thing with stability  
6 specification. Do you share the same definition?

7 MR. BLACK: Stability specification, I think  
8 there may be a dispute about what the impact of that is.  
9 We'll see how the trial progresses.

10 THE COURT: But your position is the ANDA has a  
11 release specification of 3.6?

12 MR. BLACK: That's undisputed, yes.

13 THE COURT: All right.

14 MR. BLACK: And the release specification allows  
15 them to sell a product at 3.64. It also allows them to  
16 release the product, call it released, stick it on the shelf  
17 and then sell it during the two-year shelf life. It also  
18 allows them to sell to people who will use it during the  
19 two-year shelf life, and they can't avoid infringement by  
20 making a product at 3.64 which floats up the day after  
21 they've released it, because that would be infringement.

22 So they have to make sure the product is  
23 controlled, and that's again the Tyco case, which says that  
24 you can allege infringement under 271(e) (2) (A) if there's  
25 evidence that the as marketed product will infringe even

1       though the hypothetical product specified in the ANDA could  
2       not infringe. So the 3.64 could not infringe, but if it  
3       floats up into our infringing range, that's infringement  
4       under Tyco.

5               THE COURT:     It would also be illegal under the  
6       FDA regs at some point. Right?

7               MR. BLACK:    Yes.

8               THE COURT:    They promise, they promise the  
9       FDA -- I know you say it's released. I think what they are  
10      going to say is that's a promise about stability, right, and  
11      therefore, they could not -- and the FDA would shut them  
12      down if they put on the market something that went beyond  
13      the, what you are calling the release.

14              MR. BLACK:    I do not believe there will be  
15      evidence on that in the case, Your Honor. The release  
16      is a big deal. They release the product and that's it.  
17      It's released. After they do the testing for release, which  
18      is around the time of manufacture, the product is good to  
19      go.

20              Selling that product, but if it's going to go up  
21      into the infringing range, that would be infringement just  
22      as under Tyco. Just because the ANDA says something will  
23      happen, if the real-world facts are that the product is  
24      going to change, then they have to make sure that they  
25      aren't going to make -- sell anything that's infringing.

1 That's the legal issue.

2 So we say the right question is whether the  
3 approval of Eagle's ANDA would authorize Eagle to sell vials  
4 of vasopressin that are likely to infringe during their  
5 shelf life, and we say the wrong question is whether Eagle  
6 is likely to use the full scope of that authorization.

7 Now, much of the evidence that they are going to  
8 put on is about how they have changed their in-process  
9 specification to try to avoid the product ever reaching  
10 3.64, because they know it's inevitable that if they release  
11 a 3.64, it will go into the infringing range, and we say  
12 that's legally irrelevant evidence, and we also say that  
13 they are wrong about the in-process changes because they've  
14 had no meaningful effect.

15 We're going to present two witnesses on  
16 infringement. Dr. Coralic. He's an emergency medical  
17 clinical pharmacist from UCSF in California. He'll provide  
18 some background information on how the product is used,  
19 address some of the elements of the method claims and  
20 inducement, and that will be relatively brief testimony.

21 Then we're going to call Dr. Kirsch. He's a  
22 professor emeritus at the University of Iowa and one of the  
23 specialists in peptides that Your Honor will hear from. And  
24 you'll hear from some specialists in peptides -- you'll hear  
25 from some non-specialists, but Dr. Kirsch is the leading

1 expert in the field and he will perform the infringement  
2 analysis.

3 Now, as you know, the infringement analysis  
4 has been simplified. Claim 1 of the '785 patent has four  
5 basic elements and the one we need to prove infringement on  
6 is pH. For invalidity, they need to deal with all of the  
7 elements.

8 pH testing is done as follows. A batch will  
9 have thousands of vials in it, over 25,000, 100,000 vials is  
10 possible.

11 THE COURT: How many?

12 MR. BLACK: It could be 100,000 vials in a  
13 batch. The Eagle batches are smaller. I think they are  
14 generally on the order of 28,000, 28,000 vials, and we take  
15 five sample vials from the batch. That's the standard  
16 measurement technique. You mix them together and then put  
17 them in a beaker and there's a pH.

18 The operator has to be trained to do this  
19 properly and they can measure the pH. Of course, within the  
20 five vials, each vial individually may have a slightly  
21 different pH. That's why you pool them, but that's how it's  
22 done.

23 So infringement testing and testing takes --  
24 goes throughout the life of the product. But in the real  
25 world, maybe one batch a year will have a few vials drawn

1 for it for stability testing, and they could make dozens of  
2 testing that has never been tested. That's part of the  
3 problem. No one will know that there's infringement until  
4 we're a year or two years down the road and we find a vial  
5 on the market.

6 THE COURT: You used the word stability. Do  
7 you agree that release specifications defines the property  
8 of the product that it must have on release for  
9 manufacturing?

10 MR. BLACK: Yes.

11 THE COURT: And would you agree that stability  
12 specification defines the properties post release and during  
13 the shelf life of the product?

14 MR. BLACK: No.

15 THE COURT: What's your definition of stability  
16 specification?

17 MR. BLACK: Stability specification is a  
18 specification in which they hope they will be able to meet,  
19 but if they don't meet it, which they are telling the FDA  
20 they hope they'll be able to meet, but where the evidence is  
21 going to show they can't meet it.

22 Stability specification is a guideline. It  
23 allows if they find a -- if during their stability testing  
24 that they do during the course of the life of the product,  
25 which only happens maybe once a year, they find a vial

1       that's out of specification, they will need to report it,  
2       but they don't necessarily need to withdraw the product on  
3       the market just because they found a vial that was out of  
4       specification on the pH, particularly a product like this,  
5       where the pH will drift up, and the drifting up is into the  
6       range of the reformulated Vasostrict product which is on the  
7       market. There is not going to be any evidence that the FDA  
8       is going to require them to withdraw the product from the  
9       market.

10               THE COURT:     And when you say it's something, I  
11       think you used the words "that they hope." Is that from a  
12       regulation? Where do you get your definition of stability  
13       specification?

14               MR. BLACK:    Your Honor, I fear I'm going to get  
15       beyond the evidence in the case. We had an expert on this  
16       in the Amneal case and Eagle objected to him, so we can't  
17       call him.

18               THE COURT:    Isn't it a legal issue, not an  
19       evidentiary issue?

20               MR. BLACK:    What the meaning of the stability  
21       specification is a fact issue, but the real world issue, you  
22       can read the regulation, I suppose.

23               THE COURT:    There is a regulation?

24               MR. BLACK:    There is a regulation.

25               THE COURT:    So why is it a fact question?



1                   MR. BLACK: Interpreting regulations can  
2 sometimes require expertise and input from those who are  
3 experts in the area. So they -- I don't know what evidence  
4 they are going to put on about how the stability  
5 specification binds them because they don't have any. And  
6 the reality in the industry is that it's the release spec  
7 which makes the difference, because once they release, they  
8 can let --

9                   THE COURT: The release spec is defined by  
10 regulation. Is that right?

11                  MR. BLACK: Yes. I think both of them have a  
12 regulatory definition and then practice around them. I  
13 don't think there's any dispute about what release spec  
14 means, and that's the spec that has been used in the cases  
15 and involved Tyco. It's what they are allowed to sell.  
16 They are saying we're not going to sell anything in the  
17 infringing range because it's 3.64 and that's not  
18 infringing.

19                  We say the evidence shows that they have upward  
20 drift in their products, which is unmistakable, and that the  
21 day after release they could sell the product, they are  
22 going to know that it has got -- it's inevitable they will  
23 know they are selling vials that have a pH above that level  
24 and the fact that they have a stability spec that they gave  
25 to the FDA doesn't have any consequences.

1                   THE COURT:   Okay.   Can you do me a favor, just  
2   one thing.   Their batches?

3                   MR. BLACK:   Yes.

4                   THE COURT:   I saw in the pretrial order  
5   registration batch, characterization batch, and then a third  
6   category sounds like it's optimization confirmation.   Do you  
7   mind, can you explain that?

8                   MR. BLACK:   Sure.   So the registration batches  
9   are -- the FDA requires three batches to be filed with the  
10   ANDA to make it complete.   Those are the critical batches.  
11   Those are the ones that they are representing, the ANDA  
12   filer is representing to the world is the thing that will be  
13   made.

14                   If those are withdrawn, you can withdraw a  
15   registration batch.   They could have withdrawn SVA001, for  
16   instance, and try to substitute another one but they elected  
17   not to.   So those batches are really the key.   The  
18   characterization batches come later.   I'm not sure what the  
19   difference is between registration and characterization,  
20   honestly.

21                   Optimization batches are batches that are --  
22   batches that are made by the company to optimize the  
23   specific issue or show that some area of the ANDA is  
24   going to be met, but the key ones are the registration  
25   batches.

1 THE COURT: Okay. Thank you.

2 MR. BLACK: And they can also make batches as  
3 they have in this case that they have not provided to the  
4 FDA, and that's going to be an issue Your Honor is going to  
5 have to track.

6 So the patent claims clearly are in standard  
7 form, pharmaceutical composition of such and such a  
8 characteristic or a method of increasing blood pressure  
9 where the human dosage form has a pH dosage form of 3.7 to  
10 3.9, and we say and Amneal says ordinary meaning, there's no  
11 construction.

12 You sell the product during the life of the  
13 product, then you're going to have infringement. It's not  
14 clear whether Eagle is standing on its prior assertion that  
15 these claims have to be interpreted in manufacture only, but  
16 they didn't raise that at the claim construction.

17 So as I mentioned, Eagle made three registration  
18 batches -- SVA1, 2 and 3, and they told the FDA that the  
19 specification that they were seeking release for was 3.4 to  
20 3.6, and it's undisputed that includes 3.64 and the  
21 stability specification, the same as release.

22 They did the batch testing on SVA001 and they  
23 checked it. It was released at 3.64. And they checked it  
24 periodically, and then at the end of the shelf life at  
25 24 months, they got a reading of 3.69. At that point they

1       were concerned. They thought maybe it's an operator  
2       error, maybe something wrong with the way the batch was  
3       tested, so they did another test on the same five vials.  
4       Again, those vials were pooled. Some were probably above,  
5       some below. We don't know how much. And they got a reading  
6       of 3.75 rounded to 3.8. So then they really got concerned  
7       and they pulled another five vials and got another test and  
8       got a reading of 3.68.

9               So at this point they had a Houston, we've got a  
10       problem issue, and they called in the internal investigators  
11       effectively to figure out what the root cause of the problem  
12       was. Root cause is just a fancy word in the pharm area,  
13       what caused it. And they tried to eliminate all the other  
14       potential problems -- operator error, problems in drawing  
15       the samples, problems with the pH meters, and they couldn't.

16               And so what they concluded internally was that  
17       for SVA001 stability, the pH ranged from 3.44 to 3.75.  
18       That's what they said internally was the stability of that  
19       product. And then they said the product is the likely root  
20       cause of the high pH. In other words, it's our product.  
21       It's not something else.

22               So they reported that information to the FDA.  
23       And you'll see on the far right is the, for batch SVA001,  
24       this is the rounded pH data, and it was 3.6 and 3.5, 3.4,  
25       3.6, 3.6, 3.6, and at the end at 24 months, it was at 3.7,

1 3.8 and 3.7. They reported all three values to the FDA and  
2 said that's what we found.

3 So they also provided some prose to the FDA  
4 describing what happened, and they told the FDA that the  
5 individual batches represented in Figure 1, which we'll turn  
6 to in a moment, were found statistically significant and  
7 slightly increasing over 24 months for 2 to 8 degree  
8 refrigeration.

9 So what that is saying is that if we start our  
10 product at the upper end of the pH range, we'll have upper  
11 drift. That's their words, not ours. That's what they told  
12 the FDA.

13 They also said at the bottom in yellow, the root  
14 cause of the OOS was determined to be BATCH SV001, which  
15 was released at the upper limit of the pH specification.  
16 The release value was 3.64.

17 And they provided a graph to the FDA which shows  
18 the three registration batches graphed. They got the  
19 triangle and the circles for the actual values. Then they  
20 put the predicted values that they told the FDA is what was  
21 going to happen. And because 3.64, that line is actually at  
22 3.64. Anything above it or slightly above would be in the  
23 infringing range, and we see them predicting to the FDA that  
24 based on the registration batches, they're going to have  
25 drift into the infringing range at about 13, 14 months.

1 Again, this is all their data that they presented to the  
2 FDA.

3 So the core of our infringement case which we've  
4 already discussed is that Eagle seeks FDA approval for an  
5 ANDA with an upper limit. That release is 3.64. A product  
6 released at the upper limit of the range will drift into the  
7 infringing range during its product, during its life. Any  
8 Eagle promise not to release is legally irrelevant.

9 Eagle is required to make a binding commitment  
10 to the FDA to the release specifications to resolve this  
11 issue, and if they frankly believed they had their pH under  
12 control and that they could avoid this problem, they  
13 wouldn't be maintaining that release specification of 3.64.  
14 They would reduce it to 3.55, 3.50, whatever it is, and then  
15 we wouldn't be here. So they believe they need that extra  
16 part of the range for their process for some reason.

17 I don't think there will be any testimony on it,  
18 what the reasons are, but from our perspective, it doesn't  
19 matter because we're not interested in what they are  
20 thinking. We're interested in what their ANDA will allow  
21 them to do and it will allow them to sell a product that  
22 will drift into the range.

23 Now, I want to talk about the data that we  
24 obtained after the first trial, because a huge part of their  
25 defense is that they fixed the problem. And had we gone to

1 trial back in February, we would have heard evidence from  
2 their expert that their problem had been fixed. They had  
3 made changes to their in process specifications and there  
4 won't be any more upward drift. And that turned out to be  
5 false because they made eight batches that they didn't tell  
6 us about and we delayed the trial to get the evidence on  
7 that when we received this notebook page showing three  
8 different values for batch SVA11.

9 What they did is they took values at the  
10 beginning, the middle and the end of the filling line,  
11 which is a matter of a couple of hours, and they got  
12 values of 3.54 3.56 3.57, which were above their -- 3.54  
13 is at their in process spec. 3.56 and 3.57 are above the in  
14 process spec.

15 Then what happened, they sent us another  
16 notebook page and crossed out some of the data. It turned  
17 out they had taken six values for the same batch, same time,  
18 and these numbers are all over the place.

19 The third reading that they took, which were  
20 batches, which were vials which were taken at the end of the  
21 filling line, they got value of 3.47 for one and 3.57 for  
22 another. That's a difference of a full tenth of a pH value  
23 when they've got to deal with hundredths, and their argument  
24 that they've got this pH process under control is just not  
25 accurate.

1                   What actually happened with the values as we  
2                   see here is the in-process testing is on the left, and they  
3                   test -- the bulk solution comes in a big vat, vessel, and  
4                   they test the bulk solution before they filtered it. They  
5                   run it through a filter and then they tested it again and  
6                   they got values of 3.50. But then they started filling the  
7                   vials and they pull the vials off the line and test them.

8                   They got two values, 3.51 and 3.54 and in the  
9                   middle of the filling they got 3.49 and 3.46. Then by the  
10                  time they were at the end of the filling, a couple of hours,  
11                  all on the same day, all on the day of manufacture, they got  
12                  values of 3.47 to 3.57.

13                  So we would have had this evidence at the first  
14                  trial that showed conclusively that they do not have good  
15                  control of their pH internally, which is a key part of their  
16                  case and which will be rebutted by this evidence.

17                  So at the end of the day, Your Honor, we say  
18                  that they're asking the FDA to make a product with a release  
19                  specification of 3.64. That's what counts. They know that  
20                  the day after or the month after or a couple months after,  
21                  this product is going to drift into the infringing range and  
22                  that's infringement.

23                  THE COURT: Now, I just want to go back. You  
24                  had a slide, because the slide, it seemed to show that they  
25                  represented to the FDA the release specification would be



1 the same as the stability specification. Is that what that  
2 document was?

3 MR. BLACK: Yes. The document says there's a  
4 release specification of 3.4 to 3.6 and their stability  
5 specification is the same.

6 THE COURT: Is the same. Right. That document  
7 was submitted to the FDA?

8 MR. BLACK: That is correct.

9 THE COURT: Is it part of the ANDA?

10 MR. BLACK: Yes. This data though is not part  
11 of the ANDA.

12 THE COURT: Right.

13 MR. BLACK: They have not provided this data to  
14 the FDA, and there will be no evidence --

15 THE COURT: Well, wait. They have not provided  
16 any of this data?

17 MR. BLACK: I don't believe there's -- they have  
18 not provided the data from this batch, which we got in  
19 January. They have not provided it to the FDA, no. They  
20 don't have it.

21 The FDA is not going to make a determination --  
22 there's not going to be any evidence that the FDA is going  
23 to make a determination that the product is, in fact, stable  
24 during the shelf life within that specification.

25 THE COURT: Right. But presumably, they're

1 going to say these numbers are under 3.6. What's the big  
2 deal. Right?

3 MR. BLACK: The big deal here is they wrote  
4 expert reports and they told --

5 THE COURT: That's a litigation question. My  
6 point is just in terms of why they didn't tell the FDA.

7 MR. BLACK: Oh, because they are going to run  
8 the argument that the FDA has validated their process, has  
9 said their in-process specifications are now so refined and  
10 precise, when the ANDA is approved, it's not going to  
11 release at the top of the range. That's not going to be  
12 true. You'll know it by the end of this case.

13 FDA is not looking at that kind of thing. What  
14 they will look at, the release spec permits them to sell.  
15 Case law discusses. That's what they are allowed to do.  
16 Case law says even if the ANDA says that the product,  
17 something won't happen if the product will actually turn  
18 into something infringing, that there's infringement.

19 The stability spec provides a commitment that if  
20 they find a problem, they'll discuss it with the FDA, but  
21 it's not -- it's not -- it wouldn't prevent the sale. It  
22 will only be after the fact and there will be no evidence in  
23 this case that the FDA is going to provide some kind of  
24 validation or certification that the FDA believes this  
25 product is stable, that the in process specs are -- solve

1 the problem of upward drift.

2 THE COURT: Does the label have the release  
3 spec, the stability spec, both?

4 MR. BLACK: No. The labels typically just say  
5 the solution has a pH of 3.4 to 3.6, something like that.

6 THE COURT: Right. They don't use the word  
7 release?

8 MR. BLACK: No.

9 THE COURT: They don't distinguish it? I just  
10 want to make sure.

11 MR. BLACK: That's right. The label will just  
12 say what the pH is of the solution. The release spec  
13 defines what they can sell. The release spec -- actually, I  
14 want to be more precise. The release spec says that on a  
15 given day around the time of manufacture, they will certify  
16 that the pH is no higher than 3.64. At that point they say  
17 the batch, the entire batch is released. They only test  
18 five vials for the normal --

19 THE COURT: Who is the they?

20 MR. BLACK: Eagle's partner, AMRI, who does the  
21 manufacturing, is connected to them. They will do the test,  
22 they will consult with Eagle, and then they release the  
23 batch based on a single pH reading on tens of thousands of  
24 vials, based on a five vial sample.

25 They can say it meets the spec and not violate

1 the law by saying we release test 3.64. If a month  
2 later, two months later, three months when it's either  
3 in their factory, in their warehouse or at a customer, it  
4 turns into 3.65, 3.66, which would be infringing, that is  
5 infringement.

6 The ANDA has allowed them to sell it and release  
7 it into the market. If they later catch it, then they'll  
8 have to have a dialogue with the FDA about the issue and  
9 figure out what to do, but the product will already have  
10 been infringing.

11 THE COURT: Is it your position that it's  
12 universally accepted that if the pH for a certain value,  
13 3.5 on the date of release, it's understood it's in the  
14 art that it would inevitably go up over the life of the  
15 product?

16 MR. BLACK: No, no. Actually, it depends  
17 on the -- there are variables involved in that. If there's  
18 a temperature, for instance, what you will see the data for  
19 room temperature and higher temperatures, the pH typically  
20 drops actually out of this product. It will start and it  
21 will go down in a straight line.

22 There's something about at refrigeration, it  
23 usually stays constant. It might drop. It might go up.  
24 Their product has a lot of variability in it. We don't know  
25 why, but we know it's there and we know they've actually

1       made it worse during this optimization process.

2               THE COURT:   So is it your position that the --  
3       that any expert testimony you are going to offer about  
4       changing the pH level over the shelf life of the product is  
5       product specific or is it the API specific?  In other words,  
6       it sounds like what you've just said is, it's not like if I  
7       have a generic version of Vasostrict that's released with a  
8       pH of 3.6, that I know it's going to go up, the pH level  
9       will go up.

10              You're saying it's dependent on what?  Eagle's  
11      product versus Amneal's product?  It's dependent on --

12              MR. BLACK:  Yes.  The rate of change in the pH  
13      is going to be dependent on the manufacturing and other  
14      things.

15              THE COURT:  But yours may not even increase.  
16      The reason why I'm asking is, that makes sense to me because  
17      why would the FDA release something that they know that has  
18      a release specification that matches the stability  
19      specification.  Right?  Somebody at the FDA must think that  
20      it's not inevitable that this product, the pH will rise over  
21      the shelf life.

22              MR. BLACK:  So, Your Honor, I want to resist  
23      that strongly because it's not correct, and unfortunately,  
24      there's not going to be evidence on that, on what you are  
25      talking about, because our expert on that was in the Amneal

1 case and we're not allowed to use him here. But that's not  
2 accurate and they would have to prove that.

3 The release spec allows them to sell something  
4 and they know it's going to drift into the infringing range.  
5 And any thought, Your Honor, that the FDA is somehow  
6 approving their stability spec as being some, some kind of  
7 saving grace here for what they are going to do, that's just  
8 not right. There's not going to be evidence. They are not  
9 bringing in an FDA expert to say that. Their expert on  
10 peptides said he doesn't -- he's not an FDA expert and he  
11 does not have testimony on it.

12 Stability spec doesn't matter here. It's the  
13 release spec, because that's what allows them to put an  
14 infringing product out into the world and to put it on a  
15 shelf and then sell it later, and if they know based on their  
16 internal data that it's going to infringe, that's  
17 inducement.

18 THE COURT: See, I thought you were going to say  
19 to me that -- well, you might say to me that the FDA doesn't  
20 know in part because maybe Eagle withheld information from  
21 them that if their product has a release specification of  
22 3.64 and Eagle's product is going to degrade and will end up  
23 with a stability specification that exceeds 3.6, but that  
24 the FDA, that's not what it's doing I thought. It sounds  
25 like now you're saying no.

1 MR. BLACK: Well, they are both true, Your  
2 Honor. The FDA --

3 THE COURT: Well, no, they're not, because, see,  
4 that latter argument is more acceptable to me because I  
5 can't believe the FDA would allow a product to go out on the  
6 market with the understanding that the release specification  
7 matches the stability specification unless it just believed  
8 or nothing was brought to its attention to form a belief  
9 that the product would degrade over the shelf life. That's  
10 what I'm trying to --

11 MR. BLACK: Actually, the FDA, I say they're  
12 both true because the FDA both had inadequate information to  
13 make that decision because of the way the ANDA process  
14 worked and because they don't have all of the information  
15 from Eagle. That's part of it. But they also -- also they  
16 don't see that as their job.

17 THE COURT: But how -- look, and I have dealt  
18 with the FDA in my former capacity and I can understand why  
19 you might say that.

20 MR. BLACK: I'm not saying -- I'm not --

21 THE COURT: The label as you just admitted is  
22 not -- it doesn't identify release versus stability  
23 specification. I would think that the FDA's ultimate focus  
24 has to be on at the time of administration of the drug.  
25 Now, I think obviously, to the extent that the manufacturing

1 specification affects that, it may, and is easier to monitor  
2 release specification. But ultimately, doesn't the FDA have  
3 to worry that somebody is getting an injection that doesn't  
4 have the right stability specification?

5 MR. BLACK: They actually -- the FDA, what  
6 happens is they file the ANDA and they say the release spec  
7 is 3.64 and the stability spec is 3.64. If they violate the  
8 release spec, the sale is a violation of it's misbranding, a  
9 serious violation of the law.

10 So the law said, the federal infringement law  
11 said release spec, that's important, because we're not going  
12 to assume --

13 THE COURT: I don't want to get into  
14 infringement law. I am more like on the APA.

15 MR. BLACK: Fair enough. So the release  
16 specification defines what they can sell at and we're not  
17 saying what they can release the product at after that the  
18 product goes into the world. Like in the Tyco case,  
19 sometimes the product changes when they are out in the world  
20 and they don't conform with the specification provided to  
21 the FDA and that's still infringement if you can prove that.

22 What you are saying is that you would think that  
23 the FDA would have all of these things in mind and would be  
24 making effective determination if they approved the ANDA.  
25 That won't happen, but there won't be any evidence in this



1 case on that for two reasons.

2 One is that's not really what the FDA does.

3 They approve a post-release stability protocol that says if  
4 you -- we'll allow you to monitor this by testing one batch  
5 every couple months a year and if you find an out-of-spec  
6 value at that point, you need to come back to us and talk  
7 about what to do, and they might or might not have a recall.  
8 It depends on what the issue is.

9 But the reality here is there probably wouldn't  
10 be one because the out-of-spec pH number would be in the  
11 range of the approved product so there wouldn't be any  
12 danger, but the issue is the FDA is not looking at this with  
13 the level of specificity that you seem to be assuming and  
14 they don't have all of the evidence any way.

15 THE COURT: Is there a mechanism by which  
16 a competitor can go to the FDA and say, for instance, in  
17 this case, hey, do you know that we've got reason to believe  
18 that the stability specification is not going to match the  
19 label?

20 MR. BLACK: In an ANDA case? That's why we're  
21 here, Your Honor.

22 THE COURT: No. I'm saying go to the FDA. I  
23 thought there was a procedure you might be able to do.

24 MR. BLACK: I assume -- I'm not familiar, but  
25 I'm going to go out on a limb and assume that if any citizen

1 finds that a product is not meeting the specification, that  
2 they could bring that to the attention of the FDA. Of  
3 course, nobody would know what the stability specification  
4 is because I don't believe that would be published anywhere.  
5 All you would see on the label would be the solution is 3.4  
6 to 3.6.

7 THE COURT: Okay. Thank you.

8 MR. BLACK: Okay. So on invalidity, invalidity,  
9 they have to show for anticipation, it's not clear. It  
10 seems they may have dropped anticipation last night.  
11 Regardless, we're dealing with the claim. They have to show  
12 that the pH limitation, 3.7 to 3.9 and the various impurity  
13 limitations are met concurrently in the same product.

14 It seems like we're going to hear -- we had a  
15 whole lot of prior art. It looks like we're going to hear  
16 mostly about original Vasostrict, an April 2014 label.

17 THE COURT: So I'm game if you want -- I mean,  
18 this is throwing a loop. You probably arranged you go  
19 first, Mr. Hales would go second, but I don't think it's  
20 fair you have to waste time addressing defense arguments  
21 that they are not going to pursue.

22 Do you want to wait and see what they say about  
23 invalidity and then you can present your invalidity opening?  
24 I mean, you know, because I know that happens, but --

25 MR. BLACK: I think -- I'm happy to proceed,

1 Your Honor.

2 THE COURT: All right.

3 MR. BLACK: I'm happy to proceed. We know  
4 enough. Most of the case, this is just a segue. I took out  
5 some anticipation slides because it doesn't look like it's  
6 here and this is just a quick segue to obviousness, which is  
7 really what the case is going to be about.

8 And we've got a range case here where the prior  
9 range had a range of pH of 2.5 to 4.5, which, of course,  
10 discloses 3.7, 3.8, all of those numbers. But the question  
11 is whether or not there's something special about that range  
12 or other secondary considerations, which allows you to claim  
13 a specific range along with impurity limitations, by the  
14 way, and call that an invention.

15 And the Patent Office looked at the data on that  
16 that we provided. They concluded that we had shown that.  
17 There was teaching away from the FDA where actually in the  
18 original Vasostrict approval, the FDA published information  
19 that said that the ideal range was 3.4 to 3.6, which is what  
20 the common knowledge was that 2.5 to 4.5 was the broad  
21 range. Right in the middle was 3.5, a little wiggle room on  
22 either side. That was believed to be the best range.

23 The inventors surprisingly found in the  
24 development work they were doing and they were doing alone  
25 that the best range was 3.7 to 3.9 and with the specific

1 impurity profile.

2 So the evidence in the case is largely going to  
3 turn on obviousness and whether this picture of the prior  
4 art, 2.5 to 4.5, whether that range is critical, whether  
5 there's teaching away evidence.

6 And here's the information from the FDA saying  
7 the pH of the formulation is critical because if the pH is  
8 below 3.4 and 3.6 degradation. This actually came from our  
9 ANDA. Our original NDA, we thought this was the fact at the  
10 time we filed originally and we later learned that the other  
11 range was much better and put our money behind it and  
12 actually went through the process again, spent all the money  
13 to get the product re-approved with the higher pH and  
14 launched the reformulated Vasostrict.

15 And we also filed new patents on that issue with  
16 new disclosure, which is what supports these claims, which  
17 is why even though the earliest patent in the family go back  
18 '14 or '15, but the disclosure for these claims is February  
19 of 2017.

20 There were stability data that was provided to  
21 the FDA as part of the part of the study that we did.

22 THE COURT: Hold up.

23 MR. BLACK: Yes.

24 THE COURT: September of 2017. What am I  
25 missing?

1 MR. BLACK: I thought it was February.

2 THE COURT: No, you're probably right, but that  
3 makes me think I got something wrong. All right. We'll  
4 come back to it.

5 MR. BLACK: All right. My experts are nodding  
6 their heads yes to February? Okay.

7 THE COURT: It's February. Right?

8 MR. BLACK: Yes. The Examiner reviewed the  
9 studies that had been done and was persuaded that there was  
10 criticality here and issued the claims for 3.7, 3.9, plus  
11 the other impurity limitations over the prior art. The PPC  
12 documents listed there at 2.5 to 4.5. I think they're going  
13 to argue that the original Vasostrict was closer prior art  
14 but that range doesn't overlap.

15 We have a fully overlapping here, a case which  
16 requires us to have done something significant to persuade  
17 the Examiner and we'll put on the evidence again in this  
18 case and rely on the presumption of validity. That evidence  
19 will include from Dr. Kirsch his own statistical analysis of  
20 all the data that was available, both the information  
21 available to the Examiner at the time of prosecution, which  
22 was provided by the patentee and other information that has  
23 become available since then. He will show there's  
24 statistical significance and significant difference in the  
25 impurity levels and that the 3.7 to 3.9 range is therefore

1 supported by criticality.

2 Finally, on inequitable conduct, they are going  
3 to present in an inequitable conduct case largely based on  
4 the declaration that the inventor took in a patent that's  
5 not at issue in this case and claiming that they tried to  
6 trick the Patent Office and that he was in cahoots with Greg  
7 Kenesky, a Wilson Sonsini associate who was prosecuting the  
8 case, and that they willfully presented false information to  
9 the Patent Office and they are just not going to be able to  
10 meet their burden.

11 As Your Honor probably knows, ten years ago in  
12 Therasense, the Federal Circuit tried to cut back on these  
13 claims which were being brought in 80 percent of cases and  
14 they had the catchy phrase, they have the charge of  
15 inequitable conduct. Almost every major patent case has  
16 become an absolute plague. Reputable lawyers seem to feel  
17 compelled to make the charge against other reputable lawyers  
18 to protect their client. And we have some of that that  
19 going on here when they are presenting their case, but they  
20 are not going to meet their burden.

21 Of course, on materiality they have to show that  
22 the item that was not disclosed or stated incorrectly would  
23 have been material to this case, to these patents, not to an  
24 earlier patent. And what it seems what they are going to do  
25 is try to do a three-step process for inequitable conduct.

1 First, they are going to show that the '239  
2 patent was invalid. Then they are going to show it was so  
3 bad, it's inequitable conduct. They are going to show that  
4 that should reach through in equity in this case. None of  
5 those three links will be shown, but I want to address them  
6 to be complete.

7 So their assertion centers on a declaration that  
8 was taken by the patentee during the course of the  
9 prosecution of what later became the '239 patent and that  
10 patent we refer to the refrigeration patent, refrigeration  
11 prosecution, because the claim that was in front of the  
12 Examiner at the time was this claim. And the elements  
13 above, a method of increasing blood pressure, pharmaceutical  
14 compositions with .01 to .07 and administration to a human,  
15 those, hypotensive, those have all been known for a hundred  
16 years. The Examiner was aware of that. Couldn't know  
17 anything about Vasostrict without knowing it.

18 What happened during the development project,  
19 there was an issue that Dr. Kannan was working on. They  
20 were concerned that there are two major IV bags that people  
21 would inject this stuff into, saline and dextrose. Dextrose  
22 is sugar. They were concerned that dextrose bags could not  
23 be used. Even though it had been used, that it could not be  
24 used with an approved FDA product, and so they did some work  
25 to try to determine what the problem was, and in the course

1 of that they realized that the IV bag when they were  
2 refrigerated would have an additional refrigerated six or  
3 eight hours of life.

4 It was a discovery. It did not rise ultimately  
5 to the level of patented invention, but they tried to get a  
6 patent on that and another refrigeration issue, which is  
7 they got extended shelf life to two years refrigerated and  
8 very good impurity data, which we'll have a lot of  
9 discussion about in the case, because refrigeration,  
10 refrigeration had not really been done before and they  
11 therefore got an approval for two years of shelf life  
12 refrigeration. Before this product was kept on a shelf.

13 So they tried to get these refrigeration claims  
14 approved. Dr. Kannan is clearly an inventor on that, and  
15 the inventor said, well, wait a second. I see the label for  
16 original Vasostrict and it has a comment about discard  
17 unused dilution solution after 18 hours at room temperature  
18 or 24 hours refrigeration. They said, refrigeration, well,  
19 that's two to eight degrees C. So it seems like the  
20 elements are here, but I know it is your label, so if the  
21 inventor was involved in the appropriate way with the label,  
22 we can remove the label as prior art.

23 So the declaration was prepared and it was  
24 amended right before it was prepared. And like all patent  
25 claims, the subject matter of the claims is everything



1 encompassed in total and so the declaration said the label  
2 discloses part of the subject matter of the claims, total,  
3 including A, B and C.

4 The first one is the label recites, "Vasopressin  
5 is indicated to increase blood pressure in adults with  
6 vasodilatory shock who remain hypotensive," known for a  
7 hundred years, certainly known to the Examiner.

8 And then the last two sentences, they recite to  
9 the specific thing that Dr. Kannan added. The alleged  
10 invention, refrigeration. The label recites refrigeration  
11 of the diluted vasopressin for up to 24 hours. And they  
12 wrapped it up by saying the FDA obtained this information  
13 from me and Matt Kenney, as we invented this subject matter,  
14 meaning as a whole.

15 Now, their theory seems to be what this  
16 communicated to the FDA was that the patentee and then the  
17 lawyer for Wilson Sonsini misrepresented to the Patent  
18 Office that they had invented each and every one of these  
19 things individually, including the first one, that  
20 Vasopressin is indicated to increase blood pressure in  
21 adults.

22 That's just not a comprehensive reading of that  
23 limitation, but if there's two readings of it, we win on  
24 inequitable conduct and we think our reading is right. We  
25 think there's a strain of litigation where we're headed, but

1       there's certainly no intent to deceive anyone and that's  
2       what that issue is.

3               So at the end of the day, Your Honor we think  
4       the major issues in the case are infringement, validity,  
5       inequitable conduct. We think they've dropped the other  
6       parts of this. I've seen their opening slides, which is why  
7       I say that, but to the extent they criticize the data as  
8       having been wrong, those are going to be disputes between  
9       the experts, and to the extent that they assert that various  
10      product information should have been disclosed, the  
11      Vasoprost pH was 3.4 to 3.6 and any minor material to these  
12      patents, they were not withheld with any intent. They won't  
13      be able to show that.

14             So at the end of the day, Your Honor, we believe  
15      that we'll be able to prove infringement under our  
16      Sunovion/Tyco theory and that they will not be able to  
17      resist that. We believe that they will be unable to show  
18      that there is evidence of invalidity by clear and convincing  
19      evidence.

20             THE COURT: All right. Thank you.

21             Mr. Hales, do you want to go forward? Would you  
22      like five minutes?

23             MR. HALES: I think five minutes to set up would  
24      be great.

25             THE COURT: All right. We'll take a five-minute

1 break.

2 (Short recess taken.)

3 - - -

4 (Proceedings resumed after the short recess.)

5 THE COURT: All right. Please be seated. Mr.  
6 Hales?

7 MR. HALES: May I approach just for a second,  
8 Your Honor?

9 THE COURT: Yes.

10 MR. HALES: So I just wanted to make sure --  
11 tight spacing. I may turn it when I'm using it, but I don't  
12 want to have it blocking the --

13 THE COURT: I'm not going to be able to read it.

14 MR. HALES: That's as big as I could make it.

15 THE COURT: That's all right.

16 MR. HALES: We'll have a slide for it.

17 THE COURT: That's fine. We'll get to it. Go  
18 ahead.

19 MR. HALES: Okay. Thank you, Your Honor. Good  
20 morning. Bryan Hales from Kirkland & Ellis, here  
21 representing Eagle. And it's my privilege this morning,  
22 late morning, I guess, to present the opening statement on  
23 behalf of both defendants.

24 Just by way of background, Your Honor, there's a  
25 little bit of information that we, the parties agree on, and

1       that is that this is a hundred-year-old drug, vasopressin,  
2       that we're talking about.

3               On slide 3, Mr. Black mentioned JHP. That's the  
4       predecessor of Par. This is the submission that they put  
5       into the FDA when they were trying to get approval of this  
6       hundred-year-old grandfathered drug, and as Mr. -- as Par  
7       has even conceded, this is a drug that has been on the  
8       market for 100 years. And eventually, about a decade ago,  
9       give or take, they decided to try to get FDA approval of  
10      that drug because the FDA put in a program to try to allow  
11      people to seek approval of these old grandfathered drugs  
12      that date back so far that the FDA approval process didn't  
13      even exist.

14             And so in the upper left you can see -- oh, I'm  
15      sorry, Your Honor. I've got to hand these out. May I  
16      approach?

17             THE COURT: Yes, sure.

18             MR. HALES: Are two copies sufficient?

19             THE COURT: Please.

20             (Mr. Hales handed slides to the Court.)

21             MR. HALES: So as Par told the FDA, vasopressin  
22      has been available on the market for over 98 years and they  
23      described it as a grandfathered product marketed by various  
24      companies without the approval of an NDA.

25             And then later in this submission, they told --

1 from DTX-25, they told the FDA that at the time there were  
2 numerous unapproved vasopressin products on the market, both  
3 JHP and generics, and they list some there.

4 And so they went through this approval process,  
5 and one thing that hasn't been explained is what would  
6 happen when a party went through, like JHP did, this  
7 approval process to get an old drug into the FDA system.  
8 They would get the benefit of the other generics being  
9 removed from the market.

10 Now, it's a little bit different than a normal  
11 new drug application. Right? If you go through a new drug  
12 application process with the FDA, you end up with some  
13 regulatory exclusivity for a period of time, but for these  
14 really old grandfathered drugs, what would happen is, if  
15 they got the approval process, got it approved, the generics  
16 would be removed from the market, but there wasn't some  
17 guaranteed period of long exclusivity, but the generics  
18 would just have to file an ANDA and get their way back onto  
19 the market.

20 And so what they, what they did is they  
21 submitted this, this NDA application, and importantly, they  
22 didn't have any new clinical work for this NDA. Right?  
23 They only submitted it -- it's called a paper NDA in the  
24 art. They basically put this application in for this old  
25 drug and they say it has been on the market for 98 years.

1           On the right side, DTX-38, they told the FDA  
2           Pitressin, which was the name of it at the time, because at  
3           the time of the approval process, the name changed from  
4           Pitressin to Vasostrict. It is the same product as the  
5           Pitressin drug product previously marketed by Parke-Davis  
6           since pre-1938. So they put in just the previously existing  
7           data that demonstrated the safety and efficacy of this drug  
8           that had been in the market for all of those years, not new  
9           clinical work to get through the FDA.

10           And they got approval. All right. They got  
11           approval for what we call original Vasostrict, and that's --  
12           this is from Eagle's ANDA submission, this exhibit, DTX-131,  
13           which is where Eagle says what it's seeking approval for,  
14           and under the heading that we put on there, "Original  
15           Vasostrict," which is the label that the FDA -- not the  
16           label, this is the approval description that the FDA gave  
17           Par in April of 2014 for original Vasostrict and gives some  
18           of the key characteristics of original Vasostrict. Notably,  
19           in the second row from the bottom, you can see that the pH  
20           is adjusted to 3.4 to 3.6.

21           Now, that product -- sorry. This original  
22           Vasostrict, this is admitted prior art in the case.  
23           Original Vasostrict --

24           THE COURT: I just want to go back to that sheet  
25           you just put in front of me.

1 MR. HALES: Yes.

2 THE COURT: You said this is an Eagle  
3 submission.

4 MR. HALES: Correct.

5 THE COURT: Your ANDA.

6 MR. HALES: Yes.

7 THE COURT: And you copied something. Did you  
8 literally copy or did Eagle put it together to summarize  
9 something the FDA did?

10 MR. HALES: No, no. So this, the grid is from  
11 the document, DTX-131.

12 THE COURT: Right.

13 MR. HALES: I put the highlighting on there.

14 THE COURT: Got you.

15 MR. HALES: And the redline and the red band.

16 THE COURT: Yes. But you're saying Eagle was  
17 essentially summarizing for the FDA what the FDA had already  
18 done?

19 MR. HALES: Correct.

20 THE COURT: Did it copy it?

21 MR. HALES: This information is a description of  
22 the approval.

23 THE COURT: Right.

24 MR. HALES: Right.

25 THE COURT: That the FDA gave?

1 MR. HALES: That the FDA gave original  
2 Vasostrict that comes out of the label, at least the  
3 characteristics from the approved 2014 label. What they are  
4 doing, they're comparing it. I have two more slides here.

5 THE COURT: The reason why I just wanted to  
6 understand the --

7 MR. HALES: Yes.

8 THE COURT: -- when it says inactive  
9 ingredients, and it says, adapted to adjust pH to 3.4 to  
10 3.6.

11 MR. HALES: Correct.

12 THE COURT: And you're saying that's a label?  
13 That's on the label?

14 MR. HALES: That's the approval, right.

15 THE COURT: Okay.

16 MR. HALES: The label -- what the approval  
17 document has, information slightly that is different than  
18 the label that's actually -- but I can't -- I don't know for  
19 sure if that label versus approval.

20 THE COURT: That's okay.

21 MR. HALES: I think it is actually in the label,  
22 yes.

23 THE COURT: Is adjusted pH, is there such a  
24 thing as adjusted pH in the FDA label?

25 MR. HALES: Yes. They are talking about the



1 manufacturer, right, when they say this. They use acetic  
2 acid during the formation of the drug to adjust the pH to  
3 3.4 to 3.6.

4 THE COURT: So is there a term of art, like you  
5 discussed the release specification, you heard stability  
6 specification?

7 MR. HALES: Yes.

8 THE COURT: I'm trying to figure out is there a  
9 term of art that the FDA uses called adjusted pH, and if it  
10 is, does it relate to either or both the release and  
11 stability specification?

12 MR. HALES: I don't -- I don't know if there's a  
13 term of art called adjusted pH, but what I can tell you is  
14 in the approved label as they describe the product, they are  
15 saying acetic acid to adjust pH to 3.4 to 3.6. All right.

16 Now, this was during the manufacture. In the  
17 2014 label for Vasostriect, the stability specification was  
18 wider. Right? It was wider than 3.4 to 3.6. So there was  
19 a manufacturing -- you can only adjust the pH during  
20 manufacturing, right? So the label recites that was  
21 approved, adjust to with acetic acid 3.4 to 3.6 if that  
22 makes sense.

23 THE COURT: All right.

24 MR. HALES: And then there's a different  
25 stability specification you'll hear about during trial.

1 THE COURT: All right.

2 MR. HALES: So, and they list these other items  
3 are listed in the label. They are going to use  
4 chlorobutanol, what the active ingredient is, et cetera.

5 So the other part, if we move over to the right  
6 column, Eagle also identified the characteristics in this  
7 document of the later Vasostrict label, used the ones that  
8 relate to reformulated Vasostrict.

9 And as you can see, the reformulated Vasostrict  
10 label, and this information is from the approved Vasostrict  
11 reformulated label from 2016, that they had at Par, they  
12 made some changes to their formulation and they, if we look  
13 down to the pH, second row from the bottom again, they made  
14 a change there and they used sodium acetate buffer during  
15 their manufacture to adjust the pH to 3.8.

16 All right. So that's a difference between  
17 original Vasostrict, 3.4 to 3.6, and the reformulated  
18 Vasostrict where they've changed their adjustment to pH 3.8.

19 And, finally, I've highlighted the second column  
20 and the middle column because the second column is where  
21 Eagle described its proposed ANDA product. Right. And what  
22 you can see is Eagle's proposed ANDA product tracks original  
23 Vasostrict. Right?

24 So down the second row from the bottom here,  
25 it's the most important for this case, Eagle's proposed

1 product has acetic acid used to adjust the pH to 3.4 to 3.6.  
2 Everything else in those columns from top to bottom is the  
3 same -- water for injection, chlorobutanol, conditions of  
4 use, those are all identical.

5 And you can see at the bottom underneath the  
6 chart what Eagle told the FDA is they specified, that  
7 they're specifying the original version of Vasostrict  
8 approved April 17, 2014 as the RLD. That's the reference  
9 listed drug. In other words, that's the approved drug that  
10 Eagle is proposing a copy of. Specifically, the April 17,  
11 2014 version.

12 Now, actually, before I leave that, Your Honor,  
13 one thing that you will hear in the case is, as I mentioned,  
14 original Vasostrict is admitted to be prior art as is the  
15 April 2014 label admitted to be prior art.

16 We asked Par which are the, which of your  
17 products do you contend are covered by the asserted claims  
18 in the case? They identified only the reformulated  
19 Vasostrict and they've actually said that the original  
20 Vasostrict is not covered by the claims asserted in this  
21 case. Right. So the one we're copying they admit is not  
22 covered.

23 This is going to be, Your Honor, this tension is  
24 going to appear throughout the case. Right. The case  
25 really, really is about, although they have asserted patents

1 that are directed to reformulated Vasostrict, the case is  
2 really one about original Vasostrict and it will appear  
3 throughout each of the substantive issues in the case on  
4 infringement and you've already touched on some of these in  
5 some of your questioning to Mr. Black and I will address  
6 these, but our specification doesn't infringe and it's prior  
7 art.

8 And so Par has to allege that product  
9 manufactured at 3.4 to 3.6, right, over some period of time  
10 could be deep into the shelf life for as little as five  
11 minutes you'll hear, drift up into the claim range. Now,  
12 our data doesn't show that, but it runs them squarely into a  
13 significant invalidity problem, right, because they already  
14 have a problem over original Vasostrict because of how close  
15 we will show that is prior art.

16 It has all of the properties, right, and  
17 certainly, it is in an abutting pH range, there's no dispute  
18 about that, 3.4 to 3.6 versus 3.7 to 3.9. But when you then  
19 add onto it their drift theory, the claims that they assert  
20 in the case in terms of pH are even closer to the original  
21 Vasostrict prior art because the only distinction between  
22 the asserted claims and the original Vasostrict is now this  
23 thin difference of the possibility of drift.

24 And what we'll show is that that's a huge  
25 problem because original Vasostrict was allowed to drift

1       into the claims. As I said, it had a broader stability  
2       specification than the release specification. And, in fact,  
3       original Vasostrict did drift into the claim.

4               So they can't thread the needle between these  
5       two issues trying to say we infringe and the asserted claims  
6       are somehow valid, and then it's also going to appear in the  
7       context of inequitable conduct.

8               Now, this, Your Honor, is a serious allegation.  
9       It's not one that we make lightly. But what you are going  
10      to see in the case, Your Honor, is that Par submitted not  
11      one, not even two, but three false declarations to the  
12      Patent Office in order to get these patents allowed, and the  
13      chain of prosecution and the earlier prosecution leading up  
14      to these patents, it was in the parent, and I'm going to  
15      show you some of that evidence.

16              But one of the declarations, and I'm going to --  
17      you know, in the interests of time, focus on one of them  
18      today in my remarks. One of the --

19              THE COURT: Can I just go back though?

20              MR. HALES: Yes.

21              THE COURT: You said -- so basically, I thought  
22      you just said that original Vasostrict drifts into  
23      infringement.

24              MR. HALES: Yes.

25              THE COURT: Okay.

1 MR. HALES: It was allowed to by the  
2 specification and it did.

3 THE COURT: And you all may have said this to me  
4 during the course of, you know, telephone calls and I can't  
5 say I pulled it out of the PTO.

6 So does your only -- does infringement just boil  
7 down to how I interpret federal case law? Since your  
8 product is the same as the original Vasostrict, right, is  
9 that what you are saying?

10 MR. HALES: We are -- our manufacturing  
11 specifications are actually tighter.

12 THE COURT: Well, I guess -- are you saying that  
13 your product drifts into infringement, it's just a legal  
14 issue that I've got to interpret, or you're going to  
15 distinguish your product somehow from original Vasostrict to  
16 say they drift in but yours doesn't?

17 MR. HALES: I am. It's both parts of that, Your  
18 Honor.

19 THE COURT: Okay.

20 MR. HALES: Number one, I do think this is a  
21 legal question and I will get to it in just a moment.

22 THE COURT: Right. But it's not exclusively a  
23 legal question, because you couldn't have made it more  
24 simple for me. Right? Basically just admit, yes, this is  
25 all -- I'm just trying to make sense of what I think I said

1 to Mr. Black. There's intention in the law and --

2 MR. HALES: I actually --

3 THE COURT: You're saying it's factual, that  
4 your product is similar when you need it to be but it's not  
5 similar when you don't want it to be.

6 MR. HALES: Well, I'm going to get there in  
7 about 30 seconds.

8 THE COURT: That's fine.

9 MR. HALES: If that's okay. If I can finish  
10 this thought.

11 THE COURT: All right.

12 MR. HALES: So I just wanted to preview on the  
13 issue of inequitable conduct how this 2014 label will come  
14 into play on that, too, because one of the declarations and  
15 the one I'm going to focus on today was submitted by Par by  
16 inventor Kannan and prosecuting attorney Kenesky to  
17 disqualify this very label as prior art for consideration by  
18 the Examiner and that was central to them getting these  
19 claims allowed, but it was false and I'm going to show you,  
20 unmistakably false.

21 So when we get there, that's why this 2014  
22 Vasostrict that's admitted prior art hits each of these  
23 issues through the case.

24 And so let me get right to your question now,  
25 Your Honor.

1 First off, I do think this is a case that's  
2 resolved as a matter of law and we did touch on this back in  
3 the summer and you asked some very pertinent questions to  
4 Mr. Black about this.

5 This is the Federal Circuit in Ferring in 2014.  
6 In some cases, the ANDA specification directly resolves the  
7 infringement question because it defines a proposed generic  
8 product in a manner that either meets or does not meet the  
9 limitations of the claim. Right?

10 Here, that is the case. The product that we're  
11 seeking approval of has definition. What we're asking for  
12 directly addresses the pH question. We have a release, and  
13 this is from DTX-327, a release specification of 3.4 to 3.6  
14 and a stability specification that is the same.

15 So what Par does, and Mr. Black did a number of  
16 times this morning, they only want to talk about the release  
17 specification. We're not asking for approval for a product  
18 that only worries about the release. We have release and  
19 stability.

20 So we're asking the FDA to approve a product  
21 that will be released 3.4 to 3.6 and stay there. They go  
22 hand in hand. Right? We're not asking for one without the  
23 other.

24 And I think your questions to Mr. Black were  
25 spot on in terms of questioning whether the FDA -- that the



1 regulations are we're asking for approval and they are going  
2 to approve or not approve what we asked for.

3 What we're asking for had both characteristics,  
4 release and stability, both of which are outside the claimed  
5 range of 3.7 to 3.9. So I think it is resolved and you can  
6 resolve it as a matter of law, and this really is a legal  
7 issue. There's not going to be an FDA expert in here. They  
8 could have tried to bring one. They didn't. Really, this  
9 is an issue of law and that's what the Ferring case says.

10 Now, the factual part because you asked me about  
11 the facts as well.

12 THE COURT: Now, if I rule in your favor on  
13 infringement, should I just stop there?

14 MR. HALES: Well, you could do that.

15 THE COURT: I know.

16 MR. HALES: Yes.

17 THE COURT: But should I?

18 MR. HALES: I think that would be fine. Yes. I  
19 think that would be fine.

20 Now, there is another scenario, right, and that  
21 is the situation where the ANDA specification does not  
22 address the question of infringement. And when it does not  
23 address -- or the ANDA request, right. When it does not  
24 address the question of infringement, which we do not think  
25 is the case here -- we think it does here, but when it does

1 not, the question before the Court becomes, has Par  
2 demonstrated by a preponderance of the evidence that the  
3 alleged infringer will likely market an infringing product?  
4 And as the Federal Circuit said in Glaxo, what is likely to  
5 be sold or preferably what will be sold will ultimately  
6 answer that question.

7 Now, we submit if you agree with us on part one,  
8 we're done, but if you think we need to be looking at the  
9 facts because the ANDA specification doesn't resolve the  
10 question of infringement, then you need to look at all of  
11 those facts, because the question before Your Honor is, what  
12 does the evidence suggest that we are going to manufacture  
13 and does that evidence suggest that what we are going to  
14 manufacture is likely, more likely than not going to drift  
15 up into the claimed range?

16 THE COURT: So do you agree, if I disagree with  
17 your interpretation of the law. Right?

18 MR. HALES: Right.

19 THE COURT: On the question of whether I can  
20 look beyond the ANDA.

21 MR. HALES: Yes.

22 THE COURT: Do you agree though then Mr. Black  
23 has correctly framed the question?

24 MR. HALES: No.

25 THE COURT: At that point the question would be,

1 is it more likely than not that your product will drift into  
2 the pH range?

3 MR. HALES: No.

4 THE COURT: You don't agree with that?

5 MR. HALES: I'm sorry. I answered before  
6 hearing the whole question. The question -- well, there is  
7 an issue of, there's nothing in this patent, and the  
8 inventor said none of their data has anything to do with  
9 this drift theory.

10 THE COURT: You're getting into the facts.

11 MR. HALES: Yes.

12 THE COURT: I just want to know, you guys have  
13 two different approaches to the pretrial order.

14 MR. HALES: Yes.

15 THE COURT: And Mr. Black laid out, here are the  
16 issues.

17 MR. HALES: Yes.

18 THE COURT: And one of the issues was, the issue  
19 really is, is it more likely than not that your product at  
20 some point during shelf life will infringe the patent.  
21 Right?

22 MR. HALES: Yes.

23 THE COURT: All right. And so my question is,  
24 put aside the initial ANDA question.

25 MR. HALES: Understood.

1 THE COURT: All right. Do you agree at least  
2 that that would be the question I'd have to address?

3 MR. HALES: That is the question you have to  
4 address, but there's one major thing they are doing wrong.  
5 Right? And what they are trying to do is mix and match the  
6 two concepts. Right?

7 I drew myself a grid as I was listening to Mr.  
8 Black. What they want to do is, on the specification  
9 controls part of the law, which I know is not what you are  
10 asking about, but it kind of sets this up, they want to rely  
11 on the release specification of 3.4 to 3.6, but ignore the  
12 fact that there's also a stability specification requiring  
13 the same thing and say, oh, just look at -- that's not going  
14 to happen.

15 THE COURT: Right. But then on infringement,  
16 they want to bring it back in.

17 MR. HALES: On the infringement side they want  
18 to ignore -- we say if you are going to go beyond the law  
19 and look at the data, you should look at all of the data  
20 about what's actually going to happen.

21 Par takes a different approach in that world.  
22 In that world, they don't look at what the data shows we're  
23 actually manufacturing in terms of release, right, the  
24 product down by 3.5 with their optimized process. They want  
25 to focus exclusively on the fact that the ANDA still allows,

1 allows us to release all the way up to 3.4 and then rely on  
2 the -- sorry, 3.6 and then rely on the data to show drift.  
3 Right?

4 So it's in the spec control land that we think  
5 rely on release, ignore that there's a stability  
6 specification. If we're going to look at the data world,  
7 they want to rely on what stability shows, a little bit of  
8 fluctuation, but then tack on that little bit of fluctuation  
9 to what the specification they say allows.

10 THE COURT: The specification being the  
11 stability testing?

12 MR. HALES: No. The release, the release. They  
13 would take the real world stability data, which shows a  
14 little bit of fluctuation, and then apply that to --

15 THE COURT: Sorry.

16 MR. HALES: -- hypothetical batches released at  
17 the very top of the range.

18 THE COURT: Right.

19 MR. HALES: Even though the data, which I'm  
20 going to go through in a minute, shows that we are not going  
21 to make batches at the very top of the release  
22 specification. That mixing and matching is what really is  
23 the biggest flaw in the way they view that part of the case.  
24 Right. They want to have it both ways on that.

25 So we've seen -- this is the data. If I can

1       approach?

2                   THE COURT:   Well, now I can see it.

3                   MR. HALES:   It's better up there?

4                   THE COURT:   That was sarcasm.

5                   MR. HALES:   May I approach, Your Honor?

6                   THE COURT:   You can approach.   I've got a hard  
7       copy.

8                   MR. HALES:   Okay.   And I will try to orient you.

9                   So what -- and this is the biggest board we  
10       could get and this has all data for all of the batches that  
11       we've made that have stability data associated with them.  
12       Okay.   And actually a few that don't even yet have stability  
13       data associated with them.

14                   In red, all right, the ones in red, Your Honor,  
15       are the manufacturing process that AMRI and Eagle were using  
16       before optimization to better control pH, and the ones in  
17       blue, right, around the board are the batches that were  
18       manufactured after process optimization.

19                   And they're numbered SVA1 through 17.   There are  
20       a few that were aborted for reasons that nobody is arguing  
21       are related to pH or either way in the case, not batches  
22       that are being pursued.

23                   So when we were talking to Your Honor last  
24       summer about this, there was at the time, you know, in all,  
25       the old process and the new process, every single pH

1 measurement is within the specification of 3.4 to 3.6 on  
2 release and during shelf life except one, and that one is  
3 the one Your Honor has heard about, the very last  
4 measurement at the expiration one of the very first batch  
5 that AMRI ever made. Every other one is in the  
6 specification.

7 Now, one thing we agree with Mr. Black on is  
8 that we're all happy to be here starting this case, and  
9 obviously, between the pandemic, for personal Covid, the  
10 trial has been moved multiple times, and as you know from my  
11 conversations with Your Honor, that has been -- it has been  
12 devastating to Eagle, but -- but if there's a silver lining,  
13 it's that we have and Your Honor now has an additional  
14 14 months of data, because throughout that period of time,  
15 batches that were on stability were continuing to have new  
16 measurements come out, and when new data came out, we would  
17 produce it to Par and update this board.

18 And so what you see is, as I said, we have  
19 batches now through all 24 months of stability. The top  
20 part of the board is refrigerated test conditions, the top  
21 half. The bottom left quarter of the board has what are  
22 called bridging studies, where product is part-time  
23 refrigerated, part-time at room temperature. You have  
24 those, several of those now completed, 24 months. You have  
25 others that are at 18 months now, 21 months.

1                   And in the lower right you have the room  
2                   temperature studies where shelf life is only 12 months room  
3                   temperature. Those are completed.

4                   One thing that you won't hear anybody talk about  
5                   from Par, we will, is the room temperature data. The room  
6                   temperature data shows what -- there's one bit of data here  
7                   that shows a trend up or down. They are going to say it  
8                   suggests a trend upward in refrigerated data.

9                   The data doesn't show any trend upward, and our  
10                  expert, Dr. Park, is going to go through this in some detail  
11                  with the optimized manufacturing process. All you see the  
12                  slight fluctuations, a little bit up, a little bit down over  
13                  the shelf life of the product except room temperature. Room  
14                  temperature goes down. Right? So it's getting further away  
15                  from the shelf life.

16                  Why do I say that? If you want to see a trend  
17                  in a direction, look at the room temperature data. There's  
18                  a discernible -- slight, but slight discernable downward  
19                  trend. You don't see anything the opposite in the  
20                  refrigerated data. And I would submit, Your Honor, that  
21                  that definitely is true for the optimized process. It's  
22                  also true even for the old process before we put in better  
23                  controls. Right?

24                  So this, this -- well, let me talk about SVA1  
25                  for a minute. Dr. Park is going to talk about this data.



1                   SVA1 -- let me now step back away, Your Honor.  
2                   I'm on slide 12 now.

3                   THE COURT:   Yes.

4                   MR. HALES:   This is important because SVA1 was  
5                   manufactured before Eagle was involved and before these  
6                   patents existed.

7                   So you can see from DTX-288 on the top half of  
8                   the slide the manufacturing dates for SVA1 is March 3rd of  
9                   2017.  On the bottom of the slide, excerpts of the patents  
10                  that are asserted here, they were issued in August and  
11                  September of 2017 and they didn't even publish until  
12                  June 8th of 2017, the point of that being, Your Honor, when  
13                  SVA1 was made, there wasn't any, any specific awareness of  
14                  patents out there directed to 3.7 to 3.9.  And what you can  
15                  see in SVA1's manufacturing record is that the specification  
16                  that AMRI used to manufacture SVA1 was a much broader  
17                  two-and-a-half to four-and-a-half pH specification for both  
18                  release and stability.

19                  So when they manufactured SVA1, right -- if I  
20                  can approach again, Your Honor?

21                  THE COURT:   Yes:

22                  MR. HALES:   They manufactured SVA1 and the  
23                  initial release measurement for SVA1 is, in fact, 3.64.

24                  THE COURT:   Actually, it's interesting that  
25                  you've got her the reference to both of them, and the reason

1     why I was asking about what your respective positions were  
2     going to be on release and stability in part was because,  
3     you know, when I look at paragraph 15, tab 3 of your  
4     pretrial order, you wrote, "Although the release and  
5     stability specifications for JHP unapproved for testing were  
6     pH 2.5 to 4.5."

7             You put them together and I didn't know, and  
8     that's what is -- I wanted to get a real definitive sense  
9     here, is, does the FDA, do artisans in the relevant field,  
10    do they sometimes conflate these two concepts? Do they  
11    always treat them separately? You know, is the fact that  
12    you lump them together in paragraph 15, you know, and then  
13    they're here, they're lumped together.

14            MR. HALES: I actually think they're not  
15    conflated or lumped together. Sometimes they're the same  
16    and sometimes they're different. So what you see here is  
17    that when AMRI made SVA1, their release and shelf stability  
18    specifications were both two-and-a-half to four-and-a-half.  
19    They allowed that range. Right?

20            When you get -- we get into the evidence, you're  
21    going to see that for original Vasostrict, the release  
22    specification was 3.4 to 3.6. The stability specification  
23    was broader.

24            THE COURT: So this is the very first batch that  
25    was ever run?

1 MR. HALES: This is the very first batch that  
2 AMRI made of what is now the proposed product. Right? So  
3 at the time they had and allowed for broad pH. Right?

4 THE COURT: Yes.

5 MR. HALES: And so when they made -- the point I  
6 was going to make is when this original 3.64 measurement was  
7 made, it's okay. Right? It's okay. That release. Oh,  
8 yes. The original release specification, I just got  
9 corrected because I'm talking 3.4 to 3.6 so much. The  
10 original Vasostrict release specification was 3.3 to 3.4 --  
11 3.4 to 4.0. Numbers.

12 So sometimes these change. Right? In this one,  
13 AMRI's first one, their specification was two-and-a-half to  
14 four-and-a-half.

15 THE COURT: Wait. So the original Vasostrict  
16 you're saying had a release specification of 3.4 to 4?

17 MR. HALES: 3.3 to 4.0.

18 THE COURT: And the stability specification of  
19 what?

20 MR. HALES: Stability specification, if I have  
21 it right, was two-and-a-half to four-and-a-half. Yes. Two  
22 and had a half to four-and-a-half.

23 THE COURT: Thank you.

24 MR. HALES: Over time sometimes these things  
25 change and that's what we're going to see here.

1                   So when -- so that was the way -- this is the  
2 way SVA1 was. And then eventually, and just to  
3 short-circuit it, Your Honor, eventually --

4                   THE COURT: But go back to -- go to your slide  
5 4.

6                   MR. HALES: Yes.

7                   THE COURT: So remember I asked you this  
8 question.

9                   MR. HALES: Right.

10                  THE COURT: To adjust pH, and you've got an  
11 adjusted pH there of 3.4 to 3.6.

12                  MR. HALES: Right.

13                  THE COURT: So now what is that referring to?  
14 That sounds like something different than release and  
15 stability specification.

16                  MR. HALES: Yes. It's a target. It's a target.  
17 Right?

18                  THE COURT: So I have that -- I saw that term  
19 used.

20                  MR. HALES: Yes.

21                  THE COURT: In your pretrial order also.

22                  MR. HALES: Yes.

23                  THE COURT: So let me just then go ahead and ask  
24 you about that. So that's at paragraph 36 at tab 3. And I  
25 didn't see the term being defined anywhere.

1                   Is it your position that target pH is a  
2                   regulatory defined -- regulatorily defined term?

3                   MR. HALES: I don't think -- well, I don't know  
4                   the answer of regulatory defined.

5                   THE COURT: What's the target pH then?

6                   MR. HALES: In many of these specifications you  
7                   have the allowable specification and then a target, right,  
8                   and usually, sometimes the target is narrower.

9                   THE COURT: So is there such a thing as  
10                  in-process specification?

11                  MR. HALES: Yes.

12                  THE COURT: How does that differ from target  
13                  specification?

14                  MR. HALES: Those are two different things. An  
15                  in-process specification is one usually that reflects what's  
16                  happening during the manufacturing process, for example. It  
17                  might also have a specified range and a target that's  
18                  narrower. That's exactly the case as you'll see in this  
19                  case.

20                  So, but we would -- what I think you're getting  
21                  to is --

22                  THE COURT: What's the compounding pH range?

23                  MR. HALES: This is the pH range that is  
24                  applied to the step of the manufacturing process called  
25                  compounding.

1                   THE COURT: All right. So I don't want to tie  
2 up more time on your opening, but I do think this. I think  
3 I can benefit from some clarity of the following terms, and  
4 if Mr. Black wants to chime in at some point, he may.

5                   You used these terms. You used target pH in  
6 your pretrial order. You used acceptable pH range. You  
7 used compounding pH range. You used target pH. You used  
8 release specification, stability specification, in-process  
9 and overage, and I could benefit for very simple things,  
10 essentially a one-sentence definition of all of those terms,  
11 and if both sides want to do it either today or first thing  
12 tomorrow morning, I think it would be helpful.

13                  MR. HALES: Yes.

14                  THE COURT: Go ahead.

15                  MR. HALES: Look, on slide 13, which I was about  
16 to come to, I think will answer some of those questions.

17                  THE COURT: All right.

18                  MR. HALES: So what the -- what the -- what  
19 defines the ANDA specification, let me just go to the  
20 bottom, Your Honor. What defines from the FDA and  
21 regulatory perspective, what we're asking for approval for  
22 are these release and stability specifications. Well,  
23 sorry. On the right side.

24                  This is what we're -- this is not the ANDA  
25 document, but as I've said, what we're asking for approval

1 for, and these are the formal, you know, the formal --

2 THE COURT: So the ANDA document that the FDA  
3 accepts, is it a form, you complete it?

4 MR. HALES: It's a submission. I mean, it's a  
5 big submission.

6 THE COURT: Okay.

7 MR. HALES: Yes.

8 THE COURT: Does the FDA have a box that you  
9 complete that says release specification and a box that you  
10 complete that says stability specification?

11 MR. HALES: There is a section of the submission  
12 that says here's the proposed release specification.

13 THE COURT: Let me ask the question.

14 MR. HALES: Yes.

15 THE COURT: Is it a form with a box that says  
16 FDA -- I'm trying to understand. Does the FDA say tell me  
17 what the release specification is, tell me what the  
18 stability specification is, or, no, you, the applicant, have  
19 to disclose the specification and that's what you do?

20 MR. HALES: Yes. I think what we are doing,  
21 I -- I will verify whether it's a form to be checked, but  
22 clearly, what the regulation requires is that we have to  
23 define the scope of our request for approval. These are in  
24 there.

25 THE COURT: Those two?

1 MR. HALES: Those two, release and stability  
2 specification.

3 THE COURT: Do you get FDA approval for your  
4 targeted pH or your adjusted pH or your acceptable pH or  
5 your compounding pH?

6 MR. HALES: Those are -- one second, Your Honor.

7 So when we submit to the FDA, one of the things  
8 we submit to the FDA is what's called a proposed commercial  
9 batch record, and the proposed commercial batch record  
10 outlines the manufacturing process for the, what we're  
11 asking for approval for.

12 So they see, they see the steps that we're going  
13 to go through, the equipment that we're going to use. I  
14 mean, the submission is pretty substantial.

15 THE COURT: I've seen them. They're voluminous.

16 MR. HALES: Yes.

17 THE COURT: You may not know for sure now. So  
18 again, both sides, in terms of those definitions, let me  
19 know.

20 MR. HALES: Yes.

21 THE COURT: Does the FDA specifically say, in  
22 other words, is it an FDA term of art? It sounds like from  
23 looking at the pretrial order, at the very least, it's a  
24 regulation for defining release specification. All right?  
25 I think that's right and I think Mr. Black said that and I



1 think there might be stability specification. I'm not sure.  
2 Let me know if there's a regulation that defines those other  
3 terms, too.

4 MR. HALES: I will.

5 THE COURT: All right. Thank you.

6 MR. HALES: And so let me tell you what these  
7 terms actually refer to anyway. Right?

8 So in this commercial batch record that we  
9 submit with our proposed ANDA, we describe our manufacturing  
10 process and they get a bunch of data about it. Right?

11 In our proposed ANDA process, they are not all  
12 shown here. This is a subset of it. But there is a  
13 compounding step and it has certain characteristics.  
14 There's a pH adjustment step. There's a pH stabilization  
15 step. There's an in-process, a part of the process that  
16 we call the in-process pre-filtration measurement.

17 These are -- I mean, obviously, I've focused on  
18 the batch record for this demonstrative on those parts of  
19 the process that relate to the pH measurements, but there's  
20 one then taken, what's called in-process (post filtration),  
21 and eventually they release specification and stability  
22 specifications.

23 So -- but we will, we will submit information,  
24 Your Honor, to make these things clear as requested.

25 What I wanted to point out about, again, this

1 SVA1 measurement is when you look at the process on the  
2 left, again, the red, this is the process in pertinent part  
3 that were used to manufacture SVA batches 1 through 3, which  
4 is which are the batches that Eagle and AMRI submitted to  
5 the FDA.

6 And the pH adjustment step at a requirement of  
7 3.4 to 3.6 with a target of 3.5, and then you can see the  
8 in-process pre-filtration, the in-process post-filtration,  
9 pH ranges were broad, two-and-a-half to four-and-a-half with  
10 a target of 3.4 to 3.6 in both cases. And then release was  
11 all the way out at two-and-a-half to four-and-a-half and  
12 stability, two-and-a-half to four-and-a-half when SVA1 was  
13 made. That's the way they were describing the process,  
14 performing a process.

15 Then eventually Eagle gets involved with AMRI.  
16 The patents have also issued by the time we are -- where we  
17 are now, and we put the ANDA specification in early -- I'm  
18 sorry, the ANDA request in early 2018. Everything still  
19 looked good at that point about SVA1 and it was in March of  
20 2019, recall SVA1 was manufactured in March of 2017.

21 So the 24-month stability measurement for SVA1  
22 came in in March of 2019 and that's the one that had pH that  
23 had gone higher than at that point we specified, because we  
24 had already made some narrowing of the specification.

25 And so when that happened, they did do an

1 investigation and looked at what happened and they did  
2 determine that although it was fine to have 3.64 for SVA1  
3 when it happened, it was totally within the specification,  
4 the patent didn't exist. That was what they determined to  
5 be the reason that SVA1 went out of spec at the 24-month  
6 mark, out of the then spec, right, at the time spec, because  
7 it had started at the very highest end of the 3.4, 3.6  
8 range.

9 And so they implemented manufacturing process  
10 changes with the purpose of preventing anything like SVA1  
11 happening again, and that's what you can see on the right  
12 side of the demonstrative, Your Honor. The pH adjustment  
13 step of the manufacturing process was changed -- was reduced  
14 or narrowed to 3.4 to 3.49 with the target of 3.45.

15 And so what you can see by comparing the revised  
16 process to the original one, the range was narrowed, right,  
17 the acceptable range and lowered to be further away from  
18 three point -- well, 6.4, 3.6. It's much, much lower. And  
19 as you go down, the next box down, the yellow box, pH  
20 stabilization. In the original process, there was not a pH  
21 stabilization step, so they added one. Right.

22 And that step that Dr. -- Dr. Park is going to  
23 talk about that step in detail. But you can see the  
24 stabilization step also has this lower and tighter range of  
25 3.4 to 3.5 and then again in-process filtration,

1 pre-filtration and post-filtration have this low narrow  
2 range.

3 In the end, the release and stability  
4 specifications are the same. Right? That's what's  
5 governing the FDA product. In fact, the product by the FDA.  
6 But to get there, these are the steps that we're telling the  
7 FDA that we're going to use and we are using.

8 And so let me talk to you about the  
9 stabilization step for a moment because it's important.  
10 Dr. Park is going to talk about this slide 14. I'm just  
11 going to talk about the left side of it for a minute because  
12 this is the pH adjustment and stabilization portion of our  
13 process that was added, right, for the -- after the SAV1  
14 measurement.

15 And what happens, as you can see, there's liquid  
16 in the tank. This is when they are manufacturing the  
17 vasopressin product. This is a tank that's about 35 liters.  
18 35 liters is roughly the size, Your Honor, of one of those  
19 Gatorade jugs that gets dumped onto a coach's head when they  
20 win a game just to give you some context. The volume is  
21 brought up to 95 percent QS. That basically means it's  
22 quantity sufficient. It means get the volume up to  
23 95 percent of your target, right, of your target volume.

24 And then you have a pH adjustment step. Now  
25 you're adding acetic acid. Right? That gets added at the

1 top of the batch or tank and you add acetic acid and measure  
2 pH until the pH has gotten down into this adjustment window  
3 of 3.42 to 3.49.

4 Those measurements are taken from the bottom of  
5 the tank, so you're adding at the top, you're measuring from  
6 the bottom, and there's an impeller in this tank, kind of  
7 like mixing sugar into your coffee. This impeller is  
8 stirring the liquid in there, so the objective obviously  
9 being to make this liquid uniform.

10 So once you get adjustment to 3.42 to 3.49, you  
11 move into the stabilization step. This is the new step that  
12 didn't exist when SVA1 was made or 1 through 6 for that  
13 matter.

14 And you have to wait 20 minutes while this tank  
15 is, the impeller is stirring this material around, and you  
16 take a pH measurement. It needs to be 3.42 to 3.5. If it's  
17 not, you go back up and add back to the adjustment stage.  
18 If it is, you have to wait another ten minutes, and in  
19 another ten minutes take another pH measurement, and then  
20 you have to again be within the 3.42 to 3.50, and within .03  
21 of the first measurement at 20 minutes.

22 And if that's not satisfied -- well, it could be  
23 satisfied and then you can go on in the process. It might  
24 not be satisfied because maybe that second measurement went  
25 out of 3.42 to 3.5. If that were to happen, you go back up

1 to the adjustment step and put some more acetic acid in to  
2 get the pH back down, or maybe it's within 3.4 to 3.5, but  
3 the two measurements aren't close enough to each other yet.

4 In that scenario you would go another ten  
5 minutes and another ten minutes, as long as it took to get  
6 two measurements that are within .03 of each other, ten  
7 minutes apart, and within that specified range of 3.42 to  
8 3.50, the point being that this is a period of time when the  
9 material in this tank is made uniform and consistent and  
10 down in this 3.42 to 3.50 range. This is -- and, again, Dr.  
11 Park will talk about this.

12 Now let's look at slide 15. This slide plots  
13 the pH data for batches SVA 1 through 6, right. On the top,  
14 this is refrigerated data compared to SVA 7 through 13 on  
15 the bottom, and you can see two things.

16 Number 1, as I mentioned, and I tried to show  
17 even though the numbers were on the board, for SVA1 through  
18 6, the data had already fallen in the specification even  
19 with a less controlled process except for that final 24  
20 measurement, 24-month measurement of SVA1, but it's  
21 generally sitting higher. In specification, but higher.  
22 It's fluctuating up closer to 3.6.

23 But look what we see after the optimization, SVA  
24 7 through 13. Tighter bunching of all of the stability  
25 data, and it's down -- you know, a little bit up, a little

1 bit down, right, the real-world science, but it's really  
2 centered around 3.50, 3.51, 3.52, nowhere near the 3.64 or  
3 3.65 boundary of the specification, or the 3.6  
4 specification.

5 So this is the issue that they're not dealing  
6 with properly. Right? If you're in the world where you  
7 said the specification doesn't resolve the question as a  
8 matter of law, then you need to look at all of the data, not  
9 mix and match specification versus data. And what the data  
10 shows is after the manufacturing process changes, we're  
11 nowhere near the claimed range of 3.7 to 3.9.

12 Now, they're going to talk about how we don't  
13 have to follow our in-process specifications. That's one of  
14 the arguments they're going to make. And what AMRI's  
15 director of global programming said is whether the FDA --  
16 they are going to argue the FDA doesn't make us follow any  
17 process specifications like, Your Honor asked the question.

18 Whether or not that's right as a matter of law,  
19 I think they're wrong about that, but what Dr. Aungst said  
20 is it doesn't matter. We're not going to release a batch if  
21 it doesn't conform to the in-process specification.

22 So is it likely that Eagle is going to have a  
23 product get on the market anywhere near 3.64 that would have  
24 the ability to fluctuate up into -- up to 3.65 and get  
25 rounded to 3.7 as Par suggests? The answer is no.

1                   Now, this is another demonstrative I have, Your  
2 Honor. This is a little bigger. This is blue. This is the  
3 new data. I want to talk a little bit about the specific  
4 arguments if it's okay to put in front of the other one?

5                   THE COURT: Sure.

6                   MR. HALES: So this is all of the available pH  
7 data that we have for the post-optimization process batches.  
8 That's batch 7 through 17.

9                   Now, just so Your Honor knows, the data, the FDA  
10 has been provided data regarding batches 1 through 9.  
11 Right? So they had the original six. The original were the  
12 registration, the 1 to 3. Four through 6 were  
13 characterization batches. You asked about this. That's  
14 just some batches that did some further characterization or  
15 refinements to the process.

16                   And then 7 through 9 are what we described as  
17 optimization batches, and that's because as we told the FDA,  
18 and they told all of this to the FDA. They told the FDA  
19 about seeing the 24-month measurement. They told the FDA  
20 about the investigation. They told the FDA that the issue  
21 was they believed the root cause was that it started at  
22 3.64. And they told the FDA about the process optimizations  
23 about the prior restraints I talked about to prevent it from  
24 happening again. And what the data for SVA 7 through 17  
25 showed is that it's not going to happen again.



1 All of these numbers, you can see the numbers as  
2 a whole, Dr. Park will go through this, too, have been  
3 moved, way lower, very down, down by 3.50. A little bit  
4 above, a little bit below.

5 Now, what Par is going to do and Dr. Kirsch is  
6 going to do is they are going to focus on Mr. Black said  
7 almost myopically, this little group of measurements here,  
8 these six for SVA11 that are six measurements of the initial  
9 release, initial release measurement, where these two are  
10 around, vary by .1.

11 And what they are going to do is hypothesize  
12 then that there's .1 variability throughout the data set,  
13 that we're at risk of .1 variability on all of these  
14 measurements, and then if you take that kind of variability,  
15 and again apply it to a hypothetical batch released at the  
16 upper end of the range, 3.64 or near 3.64, then you're going  
17 to drift into the range.

18 But look at -- this is one thing that Mr. Black  
19 didn't show you. If you look at SVA1, the pre-filtration  
20 measurement was 3.5.

21 THE COURT: You mean SVA11?

22 MR. HALES: 11. Thank you, Your Honor. The  
23 post-filtration measurement is 3.5. The sixth measurements  
24 of the release range from 3.49 to 3.7. The average of all  
25 six of those is 5.2.

1                   These are, the reason they're six is because  
2                   they were beginning, middle and end of the release  
3                   measurements that are done for this particular type of  
4                   batch. SVA 12 and SVA 13 are the same. We have beginning,  
5                   middle and end measurements for release.

6                   These two measurements were done by different  
7                   technicians on different days accidentally and when we, back  
8                   in January, there was all kind of suggestions of the various  
9                   conduct. I think they've abandoned this idea. The two  
10                  techs who didn't know each other had done it. They did the  
11                  measurement. The data is there for all to see. No concern  
12                  because it's all away from 3.7.

13                  But the midpoint between these, the biggest to  
14                  end one is 3.52. The midpoint between the middle, 3.53.  
15                  The midpoint between me, 3.53. And you've basically got  
16                  3.50, 3.50, 3.53 or 3.52. And then what they didn't talk  
17                  about in Mr. Black's opening is we already have six-month  
18                  stability data for SVA11 and it's one month 3.49, 3.48,  
19                  3.48. When you look at the field of data we for the  
20                  post-optimization manufacturing batches, nothing about this  
21                  data suggests the kind of variability that they are  
22                  hypothesizing would exist that would get anybody anywhere  
23                  near the claimed range of 3.7 to 3.9.

24                  So let me turn then to invalidity. Oh, sorry.  
25                  Inducement. I just have a couple of questions points on

1       inducement.

2                   This is, we believe, really an inducement case.  
3       Your Honor, for the '209 patent, it's a method-of-treatment  
4       patent. They don't even argue that we are a direct  
5       infringer, so they only have inducement available.

6                   For the '785 patent, it's a composition patent.  
7       What I think I've shown and the evidence will show is that  
8       they're going to try to say we're a direct infringer, i.e.,  
9       we are going to manufacture and sell something at 3.7 to  
10      3.9. I think that is -- the evidence defies that.

11                   So in the end, really, this is a case of  
12      inducement because they're really relying on the drift  
13      theory. It's going to leave our hands, they say, even if it  
14      leaves our hands between 3.4 and 3.6, which is clearly not  
15      infringing, that at some point over the 12 months, sorry,  
16      between 24 months of shelf life, it could dip its toe into  
17      the claimed range, could be as little as five minutes and  
18      they would say, gotcha. That theoretical five minutes at  
19      month 18 means you infringe. All right. That's their  
20      theory.

21                   In that, in that world, we're only an inducing  
22      infringer. That's the only thing they can argue. Right? I  
23      don't think we are one, but that's the only thing they can  
24      argue. And the problem is they got the law wrong on  
25      inducement. Right? They treat inducement and they said

1 this in their pretrial order like, if you just encourage  
2 somebody to do the acts that end up qualifying as  
3 infringement, in their view, that's enough for infringement.  
4 Right?

5 So if you put it into the market and you  
6 encourage a surgeon to administer somebody or a physician to  
7 administer to somebody and it happens to be that when that  
8 happened the pH had drifted up, in their world, that's  
9 enough for inducement.

10 That's not what the Federal Circuit said in DSU  
11 en banc. Inducement requires more than just intent to cause  
12 the acts that produce direct infringement. The alleged  
13 infringer, inducement requires that the alleged infringer  
14 knowingly induced infringement and possessed specific intent  
15 to encourage another's infringement.

16 And what I've shown and what you will see in the  
17 evidence, and I've gone through it already, is all of the  
18 steps that AMRI and Eagle have taken to avoid infringement.

19 THE COURT: So my only question here is,  
20 actually, as a new judge, really try to study inducement.

21 MR. HALES: Yes.

22 THE COURT: In the 12(b)(6) context and I've  
23 been pretty strict about saying you've got more than  
24 encouragement, you have to have knowledge, but this is an  
25 ANDA case.

1 MR. HALES: Yes.

2 THE COURT: And it's an artificial act of  
3 infringement. And we're positing essentially future  
4 infringement, but we're trying the case now.

5 So I'm just wondering if this is really  
6 applicable. In other words, if I conclude as a fact-finder  
7 that they're right, that you should know, which clearly, you  
8 should know in my view would not be inducement in your  
9 normal context. It wouldn't satisfy specific intent  
10 requiring inducement, but we're dealing with an ANDA. So if  
11 I conclude, and I'm not saying I am.

12 MR. HALES: Right.

13 THE COURT: If I were to conclude that, yes,  
14 their experts are right, Eagle should know that there's  
15 going to be drift into infringement of. All right? That  
16 just seems to me a little bit different situation. I mean,  
17 for instance, this DSU Med is an ANDA case?

18 MR. HALES: I don't know.

19 THE COURT: Do you not see this is a different  
20 situation? We're positing "artificial infringement."  
21 That's what the Federal Circuit said.

22 MR. HALES: Yes. I have two responses.

23 Number one, I understand your point and I think  
24 it's a reasonable question to ask and think about, but I  
25 think when you have a situation like this where we are

1 taking so many steps, and I know what you are saying, that  
2 you have disagreed with me on those. If you disagree with  
3 me on those and you've said, hey, it's all wrong. You can  
4 always --

5 THE COURT: No, no. I'm not even saying  
6 disagree. Let me say maybe I found that you really do --  
7 you guys really think that, you know, it wasn't your intent  
8 to get that pH, but let's say I find you do.

9 MR. HALES: Yes.

10 THE COURT: Right. As a factual matter. Now,  
11 because we're looking to the future, you're on notice.  
12 Right? I mean, you are on notice and we're all about, quote  
13 unquote, "artificial infringement."

14 MR. HALES: Right.

15 THE COURT: But really, it is for the purpose of  
16 determining whether there would be conditional future  
17 infringement.

18 MR. HALES: Right.

19 THE COURT: And if I find as a matter of fact  
20 that, yes, there's drift, I just -- I think to be coherent,  
21 you would have to say there's induced infringement. In the  
22 future, there's going to be induced infringement. You  
23 already know, I get to be the fact-finder. Now there's no  
24 question. You have knowledge of future infringement.

25 MR. HALES: I think the problem comes in that

1       they still can't overcome on that hypothetical, Your Honor,  
2       which is they have no ability to say when this hypothetical  
3       act would happen, because this would have to be true at the  
4       time of administration. The only thing that they have is  
5       the idea that this is going to happen. The one time it did  
6       happen --

7               THE COURT: You're getting into facts. I'm  
8       talking about if I accept their factual theory, I am just  
9       saying as a legal theory, I'm not sure I'm buying the  
10      inducement here and I kind of think it doesn't make sense  
11      because it's artificial infringement in an ANDA for the  
12      purpose of really assessing future infringement. I mean,  
13      that's the way the statutory scheme is set up.

14             MR. HALES: Yes.

15             THE COURT: So it just makes me think there  
16      should be a different test for the intent requirement for  
17      inducement in the future.

18             MR. HALES: Yes. I understand the point.

19             THE COURT: Do you know of any cases that have  
20      ever addressed this?

21             MR. HALES: I'm not aware of one that addresses  
22      this issue.

23             THE COURT: All right.

24             MR. HALES: Right. And if I get corrected on  
25      that, we'll, of course, let you know.

1           You have seen this document already, back to the  
2           fact of inducement, Your Honor. And Mr. Black shared part  
3           of it about the root cause, but what he didn't emphasize  
4           what I want to discuss, which is the very end of it, where  
5           it says what they tell the FDA.

6           This is part of Eagle's submission to the FDA  
7           after they've done this investigation of the 24-month  
8           measurement for SVA1 and they say, in order to provide  
9           greater confirmation of consistent product quality through  
10          the proposed expiry period, the manufacturing in-process  
11          controls were subsequently optimized to assure tighter  
12          control of pH is maintained during manufacturing.

13          And then they referred us to another section.  
14          That section details the optimization, the specification  
15          changes and the new batch records have been updated to  
16          commercial batch records that are proposed to reflect these  
17          new processes, and so we're telling, this is the way we're  
18          going to do it to make sure that we're not up --

19                 THE COURT: And expiry period, you just agree  
20                 that's shelf life?

21                 MR. HALES: Expiry period is through the shelf  
22                 life.

23                 THE COURT: That's going to refer them to -- the  
24                 appropriate specification for that would be the  
25                 stabilization specification.



1 MR. HALES: Correct. Correct.

2 THE COURT: Okay.

3 MR. HALES: This brings me to invalidity.

4 MR. BLACK: Objection, Your Honor. This  
5 document is likely to come into evidence.

6 THE COURT: I've got the objection, and I'm not  
7 trying to -- you don't want to waste your time because I've  
8 heard it loud and clear. I get it.

9 MR. BLACK: Thank you, Your Honor.

10 MR. HALES: Yes. I think, Your Honor, I think  
11 you said stabilization and I agreed. It's stability.  
12 Right.

13 THE COURT: Oh, stability specification.

14 MR. HALES: Right. Stability specification.

15 THE COURT: Sorry.

16 MR. HALES: I should have caught that, too.  
17 That's why I have these folks. They're helping me out.

18 So this is going to be addressed later, Your  
19 Honor, but just so you know. So we're presenting on  
20 original Vasostrict anticipation and obviousness.

21 I'm going to focus on obviousness because I  
22 think the case is so clear and the facts of anticipation are  
23 kind of a subset of that. But this lot that Mr. Black is  
24 objecting to is a lot of original Vasostrict that was sold,  
25 lot 788435. And this will be dealt with later, but the

1 information establishing that that lot was sold was produced  
2 to us, if I have the date right, or we learned about it from  
3 Amneal I think on January 8th, the Friday before we were  
4 supposed to start that January 11th trial, because they  
5 produced the sales information for that lot to Amneal in  
6 Amneal's case but not to us in our case.

7 And so when the case got consolidated and we  
8 were getting, trying to work with Amneal to sort things out,  
9 we realized, like, wait a second. We don't have information  
10 from Par that this lot was sold. Anyway, the point being  
11 that then got folded into part of the evidence that we  
12 have about original Vasostrict and that's why we're focusing  
13 on this particular lot along with the other information that  
14 they said is admitted prior art. That's to Vasostrict.

15 And what this shows, and I'm just going -- we're  
16 going to focus on pH because that's really the issue. What  
17 this lot shows is that that lot was the sold lot, has all of  
18 the impurities limitations satisfied during its life at a pH  
19 of 3.6. Right, at a pH of 3.6.

20 And as Mr. Black acknowledges, that puts us into  
21 the abutting range law. Right? The claimed range is 3.7 to  
22 3.9. We'll have every other limitation in the patent. Most  
23 of them he admitted are not controverted. Right? All of  
24 the other limitations of the claim are satisfied except this  
25 happened to be true for this particular lot at a pH of 3.6,

1 right next-door to the claim range.

2 The label, of course, also specifies 3.4 to 3.6.  
3 The original Vasostrict label description specifies a pH  
4 range of 3.4 to 3.6 of which that, you know, the lot is at  
5 3.6, the label is at 3.4 to 3.6, and you can see the claims  
6 all require 3.7, 3.9.

7 And that puts us into this area of the law  
8 that we've talked about with Your Honor, which is when  
9 you are talking about obviousness, when the claim  
10 limitations are met except for one, where you've got  
11 an abutting range, that makes a prima facie case of  
12 obviousness that the patent owner then has to rebut that  
13 prima facie case by coming forward with some kind of  
14 evidence showing that the claimed range is critical or they  
15 can try teaching away, too. I think they're going to try  
16 both. But they have to come in.

17 When you've got nothing is different between --  
18 the claim is 3.7 to 3.9 and the prior art was at 3.4 to  
19 3.6. To demonstrate that that is really something that  
20 deserves a patent, they have to come up with something to  
21 show why that adjacent range, why the claimed range is  
22 critical for that.

23 And, importantly, this --

24 THE COURT: I'm just curious.

25 MR. HALES: Yes.

1 THE COURT: So the one range ends at 3.6.

2 MR. HALES: Yes.

3 THE COURT: The claimed range is 3.7.

4 MR. HALES: Yes.

5 THE COURT: Mr. Black, do you agree that they're  
6 adjacent ranges?

7 MR. BLACK: Not from a -- I don't believe that  
8 qualifies under the patent law, but I also don't think that  
9 matters because the prior art was 2.5 to 4.5, which actually  
10 includes the values 3.7, 3.8 and 3.9.

11 THE COURT: Well, I will get to that. I just  
12 want to make -- sorry.

13 MR. HALES: Let me add one more thought on that,  
14 Your Honor. It probably doesn't matter because you've got  
15 cases about overlapping ranges, you've got cases about very  
16 close ranges that one wouldn't think make a difference and  
17 the evidence will show here that one wouldn't think it would  
18 make a difference.

19 And also remember the way they're talking about  
20 the claims when it comes to infringement. 3.6 goes all the  
21 way up to 3.64. 3.7 goes all the way down to 3.65, right,  
22 because these are only reported to one decimal place. These  
23 really are -- when the borderline between infringement and  
24 validity in their view is that hundredth of a pH unit  
25 between 3.64 and 3.65 and for as little as five minutes.

1 That's how close this is. So I submit this absolutely is an  
2 abutting range, although either way I think we're in the  
3 world where the presumption governs.

4 So they have to come up with some kind of  
5 teaching away for unexpected results evidence that  
6 demonstrate criticality. And I would also add, Your Honor,  
7 if the presumption doesn't exist, that the evidence makes  
8 out a case of obviousness in the normal context anyway, so  
9 however you look at it.

10 Let me just give you a couple highlights. What  
11 we're talking about according to them are stability and  
12 impurities. Right? This patent is supposed to be directed  
13 to stability and impurity.

14 The original Vasostrict shelf life was 12,  
15 24 months refrigerated and/or 20 -- 12 months room  
16 temperature. The reformulated Vasostrict, which is what the  
17 patents are supposed to be about, has the same shelf life.  
18 So this magical 3.7 to 3.9 range hasn't given them any  
19 benefit in that sense.

20 In terms of the impurity limits, original  
21 Vasostrict, FDA approved impurity limits on release, five  
22 percent through shelf life, 17 percent impurity. In the  
23 reformulated product that's supposed to be the result of the  
24 magic pH range, the impurity total degradation products on  
25 release, five percent. On shelf life, 17 percent, no

1 benefit that we can see there.

2 And then I mentioned in the law that the, this  
3 effort to show criticality needs to be commensurate with  
4 claim scope, right, and, again, the way they're interpreting  
5 these claims, there's nothing about this in the patent that  
6 talks about something that's manufactured at one range, 3.4  
7 to 3.6, but then at some point for some tiny amount of time  
8 drifts up to the claimed range.

9 They don't have any criticality. They are going  
10 to put a whole bunch of data in front of you, but we asked  
11 one of their inventors, Mr. Sanghvi, are you aware of any  
12 data whatsoever showing the benefit of having a pH that  
13 starts within the range of 3.4 to 3.6 at release but then  
14 goes up to 3.8 during the shelf life?

15 I don't recall such data.

16 And that was broader than the patent. I mean,  
17 it's clearly not in the patent, but he's not aware of any  
18 data.

19 Teaching away has the same problem. They are  
20 going to say some references teach away, Your Honor.  
21 Teaching away, that argument also has to be commensurate  
22 with the claim scope. And the way they are arguing that  
23 these claims cover drift theory, they are going to talk  
24 about references that have absolutely no discussion of this  
25 idea of starting at one range and then for some unknown

1 amount of time at some unknown point drifting into a  
2 different range being taught away from. So they can't show  
3 anything is commensurate with the claim scope as they're  
4 asserting them here for infringement.

5 And that brings me to unenforceability. I'm not  
6 going to spend a lot of time on the law, but I am going to  
7 spend -- the one thing that's unfortunate about this, Your  
8 Honor, is with the exception of the possibility that Mr.  
9 Kannan, inventor Kannan comes to testify live, most of this  
10 has to come in through video because they're unavailable  
11 witnesses that we can't -- we can't force to come here.

12 You know the standard. You have to have  
13 materiality and intent. But what I wanted to highlight is,  
14 as I mentioned, we're talking about unmistakably false  
15 affidavits and I'm going to preview that evidence in just a  
16 moment.

17 And when the conduct is an unmistakably false  
18 affidavit, it is material. That's what the Federal Circuit  
19 says in this Select Wireless case. There are other cases  
20 that say that, too.

21 And then on intent, of course, I'm sure Your  
22 Honor is familiar with the cases that make clear that rarely  
23 is there smoking gun evidence of intent. The Court has to  
24 look at the facts and circumstances that round the conduct,  
25 but there are also cases out there that talk about the fact

1 that when you're putting in false affidavits, that supports  
2 a strong inference of intent, can support it, and that's  
3 what we are going to show you here.

4 So Mr. Black has also said during the pretrial  
5 conference and today, you know, at the pretrial conference,  
6 why are we talking about inequitable conduct? The patent  
7 we're talking about is not even asserted. But it's very  
8 clear that the taint of the finding of inequitable conduct  
9 in one patent if it's in the chain of prosecution or relates  
10 to other patent applications and the same technology family  
11 can render them unenforceable as well. That's Therasense  
12 that reaffirmed that. That was long a case.

13 And this True Harbor case from Judge Sleet out  
14 of this district makes this point. Right? And it talks  
15 about how to think about it. A patent that issues from a  
16 divisional or continuation application may be held  
17 unenforceable where there is inequitable conduct with  
18 respect to the prosecution of an earlier related application  
19 in the chain leading to the challenged patent and the  
20 inequitable conduct relates to the asserted claims of the  
21 patent that we're challenging. We're going to show both of  
22 those things.

23 One thing you should know, Your Honor,  
24 especially what I'm going to preview today, this conduct  
25 occurred in the prosecution of the '239 patent, which is a



1 parent. Right? The '239 patent is a parent to both of the  
2 asserted patents.

3 The '239 patent was actually asserted in this  
4 case by Par against us initially, and sometime after we  
5 developed this evidence, they dropped the '239 patent. And  
6 you can see Judge Sleet -- you know, Judge Sleet correctly I  
7 think notes that if you didn't have a rule like this, then  
8 parties could sort of avoid the consequences of inequitable  
9 conduct just by filing continuations. Right? And the law  
10 doesn't allow that.

11 So we're going to show you this inequitable  
12 conduct. So this is on slide 32 here, the rejection that  
13 occurred in the '239 patent over the 2014 Vasostrict label.

14 I told you that this 2014 Vasostrict label is  
15 going to play a role in each part of the case and this is  
16 how it comes up.

17 So these inventors are prosecuting the parent of  
18 this, of patents that are asserted, and the Examiner looked  
19 at the claims and rejects the claims as anticipated or  
20 obvious under -- over the FDA label for Vasostrict published  
21 April 2014, the same one that we're focused on here and that  
22 they admit is prior art.

23 And then on the right side, then this is an  
24 excerpt of DTX-10, which is the file history of the '239.  
25 She went through and listed the information that she found

1 in the 2014 label that she was used to reject the claims  
2 they were trying again.

3 The inventor, the applicant -- this is a draft  
4 declaration on slide 33 from inventor Kannan and he talks  
5 about some of the things in the invention, sorry, in the  
6 rejection, and at the end he says, the FDA obtained this  
7 information from me and the other joint inventors.

8 Now, this is a draft that the attorney Kenesky  
9 submitted to the Examiner. The point of this, which we'll  
10 show in a minute, was that Kenesky, Mr. Kenesky, was trying  
11 to disqualify the 2014 label as prior art. Right?

12 If he could convince the Examiner that these  
13 folks -- there's a rule about this -- that these inventors,  
14 same inventors invented the art being asserted against them  
15 under certain conditions, then the Patent Office would not  
16 be able to consider the 2014 label as prior art and that's  
17 what he was trying to do.

18 So after he submitted the draft declaration,  
19 they had an interview, the Examiner and Mr. Kenesky. And you  
20 can see, and this is the -- the record of the Examiner's  
21 interview summary. She puts it in there after they speak in  
22 the file history. And you can see at the very bottom  
23 highlight here, this just confirms what I said: "The point  
24 of the discussion was Par's effort to disqualify the 2014  
25 label as prior art."

1                   And then look at what the Examiner said. The  
2 Examiner said, "You' need to amend the paragraph 7 to  
3 include a reference to all of the subject matter from the  
4 FDA reference relied upon." That was what she put in her  
5 rejection, and an unequivocal statement that one or more  
6 joint inventors invented all of the subject matter relied  
7 upon, if possible, right, because you can't disqualify the  
8 reference unless they invented all of it. Right?

9                   Applicant's representative asserted that the  
10 inventor is responsible for all of the subject matter  
11 in the FDA reference and would be able to make this  
12 statement.

13                   Now, Par is now trying to do a little bit of  
14 revisionist history, calling this, I think he referred to  
15 this as the refrigeration application. Right? If we look  
16 back at the draft declaration, this doesn't even talk about  
17 refrigeration. They didn't mention refrigeration in the  
18 draft that he put in, nor would it matter if that invention  
19 had something to do with refrigeration, because the Examiner  
20 was crystal clear, you've got to tell me that they invented  
21 all of it, everything I identify if you want to disqualify  
22 this reference and he said that he could.

23                   And so slide 35 shows the declaration as  
24 submitted by inventor Kannan, and I put the numbers on there  
25 for the statements as though they're relevant to the

1 deposition. But he goes through and they have -- they have  
2 addressed each of the points of subject matter that the  
3 Examiner relied upon in her rejection, and then look at the  
4 way they changed the sentence at the very end of paragraph  
5 7. The FDA obtained this information from me and Matthew  
6 Kenney, as we invented this subject matter.

7 So she told them you've got to tell me they did  
8 it all and they put something in that said we invented all  
9 of it. And they were successful. The Examiner withdrew the  
10 2014 label as a basis for rejection because she said the  
11 declaration, declarations -- there was another one as well,  
12 but that Kannan wanted the important one, filed  
13 November 2015 are sufficient to overcome the rejection based  
14 on the FDA label for Vasostrict from April 2014. The  
15 declaration by inventor Kannan includes an unequivocal  
16 statement that he and Matthew Kenney invented the subject  
17 matter disclosed in the FDA label and relied upon in the  
18 rejection.

19 Then we get into the case and we ask Mr. Kenney  
20 and Mr. Kannan if that's true or not, inventor Kenney's  
21 testimony. Now that you have reviewed the label -- and  
22 you're going to see this with deposition designations, with  
23 the label in front of them. Now that you've reviewed the  
24 label, can you please let me know if you worked on or  
25 contributed to any portions of this label, including any

1 content thereof?

2 Answer: I don't recall doing any work that  
3 contributed to the information on this label.

4 Inventor Kannan -- and these are numbered now  
5 because we went through, he was the one that signed it. We  
6 went through every sentence. The first one is an example of  
7 the label. This is what his declaration said at the top.  
8 The label recites that Vasostrict is indicated to increase  
9 blood pressure in adults, et cetera.

10 Question to him: "You did not invent the method  
11 to increase blood pressure in adults with vasodilatory shock  
12 who remain hypotensive, as described in the label, correct?"

13 "Answer: That is correct, I did not invent.

14 Question number two. He agreed he admits he  
15 didn't invent it.

16 Number three, number four: Every single time  
17 until the final one, refrigeration, every one up until then,  
18 he said, no, I did not invent that subject matter, but I  
19 said I did in my declaration.

20 The final one on refrigeration he said, I might  
21 have contributed to refrigeration. That's it. But they  
22 told the Patent Office they invented all of it to secure the  
23 disqualification of the reference.

24 Now, we also asked Mr. Kannan and Mr. Kenesky if  
25 they ever corrected their declaration. Did you ever tell

1 the Patent Office that you only meant that you invented the  
2 subject matter of the refrigeration conditions? Similar  
3 question to Mr. Kenesky. They don't recall ever doing that.

4 And then this is -- this one is interesting,  
5 Your Honor. We had a lot of discussion at the pretrial  
6 conference about what -- well, we had it in the context of  
7 inventor Kannan. We were fighting about whether Par's  
8 redirect of Mr. Kannan in the Amneal case could be used  
9 against him and Your Honor said, no, but I recall you  
10 saying something at some point to me. I know, I know, I  
11 know, I see your concern. You're worried about them putting  
12 up the leading questions, did you mean to mislead the Patent  
13 Office, and they're going to say no and you weren't there to  
14 listen to it, which we agreed with you. But look at this.  
15 This is one of those questions. Right? You're expecting  
16 him to say, absolutely, I did not.

17 Did you during the '239 patent prosecution, in  
18 fact, know that Mr. Kenney and Mr. Kannan did not invent the  
19 subject matter of the FDA label relied upon in the rejection  
20 by the Examiner, but withheld it?

21 I don't recall.

22 Now, you are going to see more of the  
23 testimony --

24 THE COURT: This is objected to, foundation and  
25 a privilege objection?

1                   MR. HALES: Correct, correct. And you are going  
2 to see more testimony from Kenesky and Kannan and the  
3 inventors as well.

4                   Now, I think the fact that the declarations were  
5 false is established. They've admitted it. It secured the  
6 withdrawal of a very close piece of prior art, the closest,  
7 we believe, from consideration by the Examiner in the '239  
8 patent led to the allowance of those claims, and then when  
9 the asserted patents were being prosecuted, the same  
10 Examiner.

11                   When she made obviousness rejections directed to  
12 the asserted claims, she didn't rely on the 2014 label or  
13 the rejection. She talks about the 2014 label, but she  
14 makes rejections on three, a three-patent combination as  
15 evidenced by the FDA label for Vasostrict. Right? These  
16 two excerpts from are the two asserted patents on the top,  
17 and the third excerpt on the bottom talks about what that  
18 reference as evidenced by the FDA label means.

19                   She says, the FDA label for Vasostrict provides  
20 evidence that a milligram is equivalent to 530 units of  
21 vasopressin. So she used that as evidence of mathematical  
22 formula, a conversion of milligrams to units. And she  
23 acknowledges that, and she uses that conversion as part of  
24 her rejection and acknowledges that it's appropriate to do  
25 so because she can use the label as an evidentiary reference

1 and it does not need to be prior art to do so.

2 So that's recognition. She knows that she's  
3 also treating the FDA label as disqualified as prior art  
4 based on the prior submissions, submission of Kannan in the  
5 parent prosecution, and is restricting herself to only  
6 referring to it as an evidentiary record, not prior art.

7 So this is directly related to the fact that  
8 they got these asserted patents that are here today about  
9 through the Patent Office. They didn't have to deal with  
10 the 2014 label because they got it disqualified.

11 The other declarations, Your Honor, relate to  
12 the criticality evidence that they are going to put in, the  
13 false declarations. And we've got another one that we're  
14 going to show you the evidence, but in the interests of time  
15 I will stop other than to say I find this an interesting  
16 case because you can wonder like, how are we here having a  
17 trial about a proposed copy of admitted prior art?

18 This is how. Right? They got that piece of  
19 prior art disqualified from consideration of the Patent  
20 Office on the basis of a false declaration and then have to  
21 try to stretch the claims that are at a different range by  
22 allowing for this drift theory to try to reach back and grab  
23 the very prior art.

24 I mean, we're trying to get this that generic  
25 product of the original formulation on the market, the one



1       they say is not covered by the claims. We're not trying to  
2       get a generic version of the reformulated product on the  
3       market.

4               And with that, I will stop unless you have any  
5       more questions.

6               THE COURT: No. Thank you very much. They were  
7       both excellent opening statements. I commend counsel.

8               All right. Should we just go right -- do you  
9       all need a break? I want to keep moving.

10              MR. BLACK: Can we take a five-minute break?

11              THE COURT: That's fine. Try to keep it to five  
12       minutes. I will try to do it myself. Thank you.

13              (Short recess taken.)

14              - - -

15              (Proceedings resumed after the short recess.)

16              THE COURT: All right. Please be seated. Mr.  
17       Black?

18              MR. BLACK: Your Honor, we're prepared to  
19       proceed. We'll open the case.

20              We assume that all of the stipulations that are  
21       in the pretrial order or made at the pretrial conference are  
22       of record, we don't need to brief them.

23              THE COURT: Correct.

24              MR. BLACK: And then we will therefore call our  
25       witness, Zlatan Coralic, and Mr. Rhoad will handle the

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1 examination.

2 THE COURT: All right. Mr. Rhoad, do you want  
3 to approach?

4 MR. RHOAD: I understand, Your Honor,  
5 logistically, you have those binders for the witness.

6 THE COURT: Already in front of me.

7 MR. RHOAD: Yes.

8 THE COURT: Thank you.

9 PLAINTIFFS' TESTIMONY

10 ... ZLATAN CORALIC, having been duly  
11 sworn/affirmed as a witness, was examined and testified as  
12 follows...

13 THE COURT: Just a point of housekeeping. I've  
14 got a screen down here under the bench, so when the witness  
15 is testifying, don't think I'm being rude to you looking  
16 kind of in your direction but not at you. I will try to  
17 remember to tell the other witnesses. All right? Go ahead.

18 MR. RHOAD: Thank you, Your Honor. Good  
19 morning.

20 DIRECT EXAMINATION

21 BY MR. RHOAD:

22 Q. Good morning, Dr. Coralic. Will you please tell us,  
23 what is your profession?

24 A. Yes. If I can have the first slide, please. I'm an  
25 emergency medicine clinical pharmacist.

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1 Q. And where are you employed?

2 A. I'm employed by the UCSF Medical Center.

3 Q. And what is a clinical pharmacist?

4 A. Yes. So most folks are familiar with pharmacists,  
5 community pharmacists that you meet at Walgreens and CVS  
6 that prepare your medications and dispense. We also have  
7 hospital pharmacists which do similar things. They're in  
8 charge of receiving the medication, storing it  
9 appropriately, and then distributing it throughout the  
10 hospital. They also mix the medications and compound them  
11 for safe use of administration to patients.

12 Hospital pharmacists can also pursue additional  
13 training, such as a residency training, analogous to what  
14 physicians go through to become clinical pharmacists and  
15 also obtain board certification as I have.

16 Q. And do you have other roles at UCSF?

17 A. Yes. So I work as a clinical pharmacist primarily. I  
18 also have positions in UCSF School of Pharmacy and School of  
19 Medicine where I teach as an assistant professor at the  
20 School of Medicine and an associate professor at the School  
21 of Pharmacy.

22 Q. And how long have you been a clinical pharmacist at  
23 UCSF?

24 A. I've been at UCSF since I finished my residency in  
25 July of 2009.

Colaric - direct

1 Q. And what educational degrees do you have?

2 A. I have a Pharm.D., doctorate in pharmacy. I also have  
3 a doctorate.

4 Q. Okay. Dr. Coralic, can you please tell us whether you  
5 have any -- whether during the course of your career you've  
6 developed any knowledge or expertise regarding the use of  
7 administration of vasopressin products?

8 A. Originally, when I was a student pharmacist working at  
9 UMC in Las Vegas, which is a county hospital there. I  
10 prepared the medication, intravenous drip to be infused, and  
11 then during my training and subsequently working in the  
12 Emergency Room, I used vasopressin many times and sometimes  
13 even administered it to a patient.

14 Q. And what exactly is vasopressin?

15 A. So vasopressin is a hormone, which is also a  
16 medication that can be used to raise a patient's blood  
17 pressure.

18 The way that vasopressin works, Your Honor, as a  
19 kid, if you ever held a water hose at the end and squeezed  
20 the end of it to make the water pressure higher to shoot  
21 longer. Vasopressin essentially does that. It clamps down  
22 on all of the blood vessels in our body, which increases the  
23 blood pressure to our vital organs -- heart, brain, lungs.

24 Q. If you could take a look at PTX-779 in your binder,  
25 please. Can you tell us what that is?

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1 A. PTX-779 is my CV.

2 Q. Okay. And does that set forth additional information  
3 about your background and experience as a clinical  
4 pharmacist?

5 A. Yes. My CV contains my peer-reviewed publication, the  
6 book chapters that I've authored and my speaking engagements  
7 on state, local and national levels.

8 MR. RHOAD: Your Honor, at this point we would  
9 offer Dr. Coralic as an expert regarding the clinical use  
10 and administration of intravenous drug products, including  
11 vasopressin.

12 MR. LASKY: No objection, Your Honor.

13 THE COURT: Okay. Thank you.

14 BY MR. RHOAD:

15 Q. Dr. Coralic, let's start with some background about  
16 Par's vasopressin product. Are you familiar with  
17 Vasopressin?

18 A. Yes. I am familiar with Vasopressin and I use  
19 Vasopressin in my current practice.

20 Q. So what is it?

21 A. So Vasopressin, generic name vasopressin, is a  
22 medication. It's in two vials, ten milliliters and a one  
23 milliliter vial that's intended for single use.

24 Q. And how is it administered?

25 A. Yes. So the drug, once again, is given to patients

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1     who are very, very sick who have low blood pressure.

2             If we look at the label, Your Honor, you'll  
3     frequently see words such as septic shock or post-cardiotomy  
4     shock. Shock implies that there's a state of low blood  
5     pressure, that we need to do something to elevate it.

6             If I can have the next slide, please.

7             So this is the most common scenario that I  
8     encounter in the emergency department. When a patient is  
9     coming in who is very, very sick, who has some type of  
10    infection, once the infection spreads through the rest of  
11    the body, vasodilatation occurs, vasodilation while the  
12    blood vessels dilate into dilation. In turn, that will draw  
13    the blood pressure down, which can be very dangerous.

14            What we do for those patients is resuscitate  
15    them. We give them intravenous fluid. We try to get the  
16    blood pressure up. We'll give other blood pressure  
17    supporting medication. In the labels you often see the word  
18    catecholamine. That means use another blood pressure  
19    medication. There's one commonly called Norepinephrine.

20            If all of those things do not work, we'll move  
21    onto a second blood pressure agent. In this case it would  
22    be vasopressin or Vasopressin. The way that the drug is  
23    given, I would withdraw the one ml from the vial. I will  
24    further dilute it in a compatible IV fluid.

25            At that point that drug will be hooked up to a

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1 pump and delivered in a controlled manner to the patient.  
2 The drug is very, very potent, so we have to be very careful  
3 how the drug is administered. If we give so much, it can  
4 cause so much vasoconstriction that it can lead to ischemia,  
5 where there's no blood supply to our arms and legs. Worst  
6 case scenario, it can cause a heart attack or a stroke.

7 Q. Is the treatment regimen using vasopressin that you  
8 just described something that is taught in the  
9 patent-in-suit?

10 A. If I can have the next slide, please.

11 So if we look at the '209 patent in the  
12 teachings, this is exactly what's described. For example,  
13 the indication states that it's intended to include increase  
14 blood pressure in patients with vasodilatory shock, and that  
15 is that shock resulting from vasodilation due to infection  
16 or cardiac surgery.

17 The drug is packaged in one millimeter vials  
18 that is supplied at a concentration of 20 units per ml, and  
19 there are also teachings about how to safely administer via  
20 an IV drip. Let's talk about how to dilute it and a dosage  
21 that should be given.

22 Q. And do intravenous and other drug products have what  
23 is referred to as a shelf life?

24 A. Yes. If I can have the next slide, please.

25 So all medications that are supplied by the

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1 manufacturer will have a label on the actual vial or on the  
2 drug carton itself, and that label will have a lot number  
3 and expiration date. That would indicate to us what that  
4 drug shelf life is. To me, as a pharmacist, what that means  
5 is that I can safely use their drug up until the expiration  
6 and give that drug to the patient.

7 Q. And can you give it as late as a day or week prior to  
8 the expiration date?

9 A. Yes. Technically, we can give the drug all the way up  
10 until the last day, last hour of the expiration date.

11 Q. And how is Vasostrict typically stored before it gets  
12 administered in the hospital?

13 A. Yes. So usually, we will receive the medication cold.  
14 It's refrigerated. We'll either store it in the  
15 refrigerator or place it at room temperature, depending on  
16 which part of the hospital the drug is being delivered to.  
17 It will remain in the refrigerated condition until we do  
18 take it out of the refrigerator. If we do have to do that,  
19 we have to change the label from the expiration date to  
20 12 months from the time that it was withdrawn from the  
21 refrigerator.

22 Q. All right. Let's turn then to the product that's  
23 accused of infringement in this case, Eagle's proposed ANDA  
24 product. What's your understanding as to what that product  
25 is?



Colaric - direct

1 A. Yes. If I can have the next slide, please.

2 So as I understand it, Eagle's product will be  
3 the same, one milliliter vial of vasopressin at  
4 20 millimeters per ml. It has the same active ingredient,  
5 which will be vasopressin. It's going to have the same  
6 indication for use and the same storage condition.

7 Q. All right. And if Eagle's ANDA product were to be  
8 approved by the FDA, how would it be administered to  
9 patients?

10 A. Yes. If I can have the next slide, please.

11 I would expect that Eagle's proposed product to  
12 be given in the same way that we use Vasopressin today, which  
13 is we would obtain the vials. We'll dilute that with a  
14 compatible IV fluid, hook it up to a pump and slowly  
15 administer it to a patient.

16 Q. And what's the basis for your understanding that that  
17 is the way this product would be administered?

18 A. That would be the proposed package insert.

19 Q. And the proposed package insert for Eagle's product is  
20 at PTX-1417 in your binder; is that right?

21 A. That's correct.

22 Q. Now --

23 THE COURT: Can I ask a stupid question? So I'm  
24 in the hospital and the doctor decides whether or not a  
25 person is going to get this drug.

Colaric - direct

1 THE WITNESS: Generally speaking, that's  
2 correct.

3 THE COURT: Right. Is there always a pharmacist  
4 on duty such that then the doctor in the hospital setting,  
5 the doctor still has to get some pharmacist to take the drug  
6 out of the storage facility and give it to another  
7 healthcare provider? Is that right?

8 THE WITNESS: So it depends on which part of  
9 hospital we're talking about. If we are just talking about  
10 a hospital as a whole, there will be a pharmacy department  
11 in that hospital and that drug would have to be dispensed  
12 from the pharmacy to the bedside to be used.

13 Now, there are certain places such as anesthesia  
14 where physicians have access to the drug themselves and they  
15 can take it and dilute it. Many times in those cases  
16 they'll give the drug at room temperature because it's going  
17 to be on a cart rather than refrigerator. It depends where  
18 in the hospital the patient is being taken care of.

19 THE COURT: And does the doctor decide -- in  
20 this case, there's only one vasopressin on the market?

21 THE WITNESS: Correct.

22 THE COURT: All right. Does the doctor decide  
23 if there are multiple brands or does the hospital store  
24 multiple brands of the same drug?

25 THE WITNESS: So each hospital has a pharmacy

Colaric - direct

1 therapeutics committee. They'll have extensive reviews  
2 about the drugs that are available and they will decide  
3 which drug they're going to acquire and store.

4 In the case of Vasostrict, there's only one  
5 product and that's the product that's pretty much carried  
6 everywhere.

7 THE COURT: But let's say there was a generic on  
8 the market. First of all, would a hospital only have one  
9 brand or would they have two brands maybe or more?

10 THE WITNESS: Generally speaking, it will just  
11 be one brand. Hospitals try to control costs, so whatever  
12 is most cost efficient in that hospital, that's the drug  
13 they would choose.

14 THE COURT: All right. And when the doctor  
15 prescribes it, is the doctor prescribing just the active  
16 ingredient or is the doctor prescribing the particular  
17 brand?

18 THE WITNESS: They will prescribe for the  
19 generic ingredient.

20 THE COURT: All right.

21 BY MR. RHOAD:

22 Q. Now, in your experience, do clinicians typically  
23 follow the instructions provided by the manufacturer for  
24 dosing and administering the drug product?

25 A. Yes. Whenever there's a question how to give the drug

Colaric - direct

1 safely, how to mix it and administer it, we would look to  
2 package insert for that instruction.

3 Q. Would you expect that to be true for Eagle's proposed  
4 ANDA product?

5 A. I do.

6 Q. All right. With that background, let's turn to your  
7 infringement opinion in this case. Are you familiar with  
8 U.S. Patent No. 9,744,209, which we all refer to as the '209  
9 patent?

10 A. Yes, I am.

11 Q. And is that JTX-2 in your binder?

12 A. JTX-2 is the '209 patent, that's correct.

13 Q. And did you conduct an analysis as to whether or not  
14 the use of Eagle's ANDA product would infringe the '209  
15 patent?

16 A. Yes. If I can have the next slide, please. Yes, I  
17 did.

18 Q. And what did you do as far as conducting your  
19 infringement analysis?

20 A. So I reviewed the '209 patent and its claims. I also  
21 reviewed the Court's claim construction and I also reviewed  
22 the proposed package insert for Eagle and other documents  
23 that were submitted.

24 Q. And what legal standard did you apply in conducting  
25 your analysis?

Colaric - direct

1 A. Yes. Your Honor, I'm not a patent lawyer, probably  
2 the least experienced patent law person in this room today,  
3 but the way that I understand, I understand it can be direct  
4 infringement when somebody performs all the steps of the  
5 claimed method and it could be indirect infringement,  
6 specifically inducement, where somebody instructs somebody  
7 to perform all steps of the claimed method. My  
8 understanding was that in cases of pharmaceutical products,  
9 that's done with a package insert.

10 Q. Now, after having conducted your analysis, did you  
11 reach a conclusion as to whether Eagle's use and sale of its  
12 ANDA product would infringe claims 1, 4, 5 and 7 of the '209  
13 patent?

14 A. Yes, I did.

15 Q. And what was your conclusion?

16 A. My opinion is that it would.

17 Q. And what materials specifically did you rely on in  
18 reaching that conclusion?

19 A. If I can have the next slide, please.

20 So I relied on the proposed package insert and  
21 the proposed labeling for the actual cartons and the label  
22 that's going to go on the vial and also the documents that  
23 specify the requested shelf life.

24 Q. And we talked about the proposed package insert. Is  
25 the proposed labeling for the packaging PTX-1419 in your

Colaric - direct

1 binder?

2 A. That's correct.

3 Q. And is the proposed labeling for the vial PTX-1420?

4 A. Yes. 1420, that is correct.

5 Q. And is the document relating to the requested shelf  
6 life PTX-1422?

7 A. That's correct.

8 Q. Now, did you also rely in part on another expert in  
9 this case?

10 A. Yes. I relied -- Your Honor, how I dichotomized it  
11 just in my mind for simplicity, there are clinical-related  
12 claims and methods and their formulation-related method. I  
13 focused on the clinical part and I referred the other stuff  
14 to Dr. Kirsch.

15 Q. Now, what shelf life is Eagle seeking for its product?

16 A. If I can have the next slide, please. As I understand  
17 it, Eagle is seeking the same shelf life as Vasostrict,  
18 which will be 24 months in refrigerated conditions, and in  
19 those cases it would have to be stored at room temperature,  
20 the shelf life will change to 12 months.

21 Q. For that you're referring to PTX-1422 at pages 126 to  
22 127; is that right?

23 A. That's correct.

24 Q. And would you expect that Eagle's ANDA product would  
25 be stored by pharmacy departments and hospitals in the same

Colaric - direct

1 way that Vasostrict is stored?

2 A. I would expect that the drug would be shipped in a  
3 similar manner, meaning we would receive it in cold tote and  
4 then pharmacists would store it in refrigerated conditions  
5 or room temperature, whatever is necessary.

6 Q. Now, a moment ago you said that you had concluded that  
7 the sale of Eagle's ANDA products would induce infringement.  
8 Asserted claims of the '209 patent. What's the basis for  
9 your conclusion in that regard?

10 A. If I can have the next slide, please. So, once again,  
11 there are a set of two things at issue here, the clinical  
12 part and the formulation related things.

13 My understanding is that Eagle has stipulated to  
14 all issues besides the pH issue.

15 If I can have the next slide, please.

16 When it comes to '209 patent and I will go into  
17 detail for each of the clinical ones. Claim 1, you'll see a  
18 of these limitations have been stipulated besides the pH  
19 issue, which we discussed.

20 I also understand there's an issue with claim 4,  
21 5 and 7, which are the dependent claims under claim 1, so if  
22 claim 1 is infringed, these claims are infringed.

23 Q. Now, who would be the people who would actually be  
24 performing the claim method using Eagle's ANDA product?

25 A. If I can have the next slide, please. So there's one

Colaric - direct

1 claim method which has to do with administration. Most  
2 typically, that will be done by the bedside nurse, although  
3 it can be done by physicians and anesthesiologists. In some  
4 cases within my practice I'm allowed to give drugs. I will  
5 be able to administer the drug as well.

6 Q. And how would Eagle be inducing those people to  
7 perform the claimed method?

8 A. So once again, using the definition that I understand,  
9 by following the instructions on the proposed package  
10 insert.

11 Q. And can you take us through the package insert and  
12 tell the basis for your statement that the package insert  
13 would induce people to perform the clinical aspects of the  
14 claimed method?

15 A. Sure. If I can have the next slide, please.

16 If we look at claim 1, this is the first claim  
17 that deals with the method of increasing blood pressure in a  
18 patient who needs it, and the proposed package insert, if we  
19 look under indications and usage, the drug will be indicated  
20 to increase blood pressure in patients with vasodilatory  
21 shock, especially those patients who may have hypotensive  
22 despite fluids and catecholamines.

23 The next slide. Administering to the human a  
24 unit dosage form. If we look at if package insert, this  
25 will tell the physicians how to dose and how to administer



Colaric - direct

1 it. Under dosage form, it will tell us how the drug will be  
2 supplied as one milliliter vial with 20 units per ml. If we  
3 look under the preparation of the solution, that will tell  
4 us how to dilute the drug and administer it to the patient.

5 If I can have the next slide, please.

6 This part here deals with the actual dosage  
7 that's recommended for vasopressin. The claimed dose is  
8 0.01 units per minute all the way up to 0.1 units per  
9 minute.

10 If we look at the package insert for septic  
11 shock and post-cardiotomy shock, we can see that that claim  
12 falls within that range of 0.01 to 0.1.

13 I think I have one more. For a patient who has  
14 very low blood pressure, who is hypotensive, once again, the  
15 indication and usage, so it will be indicated for adults who  
16 remain hypotensive.

17 Q. Now, does the product package insert instruct  
18 clinicians to test the product for pH before they administer  
19 it to patients?

20 A. It does not instruct physicians to test for pH before  
21 administration.

22 Q. Do physicians test for pH before they administer it?

23 A. We do not test for pH before it's given to the  
24 patient.

25 Q. Would you expect clinicians to know what the pH is of

Colaric - direct

1 Vasopressin's product is at the time it's administered?

2 A. As clinicians, we would not know what the pH is in  
3 each vial before we use it.

4 Q. In your opinion, how is it that induced infringement  
5 will be occurring?

6 A. The next slide, please.

7 Your Honor, can I just summarize where we are.  
8 We have the Eagle proposed product that if it comes on the  
9 market, it will have a shelf life of 24 months or 12 months,  
10 depending on the storage condition.

11 As I understand it, if at any one point in time  
12 that drug is given and it satisfies the pH limitation, that  
13 there will be inducement to infringe. I as a clinician  
14 would be infringing directly and Eagle would be inducing  
15 through package insert.

16 If I could have the next slide, please.

17 To kind of summarize, all the other issues here  
18 have already been stipulated besides the pH issue. If that  
19 pH issue is true, then that would result in infringement.

20 And the next slide, please.

21 We'll look at the dependent claims 4, 5 and 7.  
22 If one would be infringed, all of these other ones would be  
23 infringed as well.

24 MR. RHOAD: Thank you, Your Honor. I have no  
25 further questions at this time.

Colaric - cross

1 THE COURT: Thank you.

2 MR. RHOAD: I was going to wait until the end of  
3 the testimony. I guess I would like to move the admission  
4 of documents that he referred to, which would be JTX-2,  
5 PTX-1417, PTX-1419, PTX-1420, PTX-1422, and his CV, PTX-779.

6 MR. LASKY: No objection.

7 THE COURT: All right.

8 (JTX-2, PTX-1417, PTX-1419, PTX-1420, PTX-1422  
9 and PTX-779 were admitted into evidence.)

10 CROSS-EXAMINATION

11 BY MR. LASKY:

12 Q. Dr. Coralic, good morning. My name is Benjamin Lasky.  
13 I'm going to be asking some questions on behalf of defendant  
14 Eagle.

15 A. Good morning.

16 Q. So in your direct you described how vasopressin is  
17 handled and used in practice; right?

18 A. Correct.

19 Q. And if we can pull up slide 5 from your  
20 demonstratives. And you testified that the patent describes  
21 the way vasopressin is used consistent with how it's used in  
22 practice; right?

23 A. Correct.

24 Q. Now, of everything you've discussed, including this  
25 portion of the patent, nothing there was new as of 2017; is

Colaric - cross

1       that right?

2       A.       2017? I think we've used vasopressin in the same  
3       manner before then and up until now.

4       Q.       And in this case you won't be offering any opinions  
5       about the validity or enforceability of the patents-in-suit;  
6       right?

7       A.       No.

8       Q.       And your opinions are limited to the '209 patent; is  
9       that right?

10      A.       That's correct.

11      Q.       So you won't be giving any opinions that Eagle is  
12      likely to infringe the '785 patent; is that correct?

13      A.       Correct.

14      Q.       And regarding the pH limitations, you're not  
15      independently assessing those limitations, are you?

16      A.       That's correct. I'm relying on another expert for  
17      that.

18      Q.       You agree that in the package insert that you  
19      testified about, the only pH mentioned is the 3.4 to 3.6 pH;  
20      is that right?

21      A.       Correct.

22      Q.       And for the '209 patent, of course, you have not  
23      opined that Eagle itself will administer its vasopressin  
24      product to patients; is that right?

25      A.       That's correct.

Colaric - cross

1 Q. Okay. Can we pull up slide 9, please. Now, this is  
2 the slide that you used to explain the legal standards you  
3 applied in this case; is that right?

4 A. That's correct.

5 Q. And you admitted you're not a lawyer and you have no  
6 independent knowledge of patent law; is that right?

7 A. No, sir.

8 Q. So you have no independent knowledge that the  
9 standards that were provided to you are correct; right?

10 A. Right. That's how I interpreted them.

11 Q. Right. You relied on Par's lawyers to give you the  
12 legal standards you're applying; right?

13 A. The definitions, yes.

14 Q. And you have not offered an opinion that Eagle would  
15 have any specific intent to do anything; right?

16 A. No.

17 Q. So I'd like to ask you a little bit about your own  
18 personal experience with vasopressin.

19 A. Sure.

20 Q. So you personally started using vasopressin products  
21 when you were in pharmacy school in around 2006, 2007?

22 A. Yes. When I worked as an intern in that hospital in  
23 Las Vegas.

24 Q. Right. At that time you understand that was an  
25 unapproved product; right?

Colaric - cross

1 A. I'm not sure what the approval status was. I know we  
2 were clinically using it.

3 Q. It was a generic product. It wasn't approved by the  
4 FDA at that point?

5 A. As far as I can recall, correct.

6 Q. And although it didn't have an FDA approved  
7 indication, you were using it to treat hypertension; right?

8 A. Hypotension.

9 Q. Hypotension. And then at some point in the last  
10 decade you learned that vasopressin had gone from a generic  
11 drug to a branded drug called Vasopressin; right?

12 A. Right. That was noticeable in clinical practice  
13 because we all of a sudden had a new product that we were  
14 working with.

15 Q. Sitting here today, you know at some point Par  
16 reformulated Vasopressin?

17 A. From previous depositions and things I learned today,  
18 I know that to be the case.

19 Q. Right. You learned about the reformulation of  
20 Vasopressin in this case; right?

21 A. Correct.

22 Q. You didn't learn about the reformulation in your own  
23 practice; right?

24 A. Correct. Clinically, it was not apparent to us.

25 Q. Right. So that means there was no change to your

Colaric - cross

1 practice as a result of the reformulation of Vasopressin;  
2 right?

3 A. Generally speaking, that's correct. There were some  
4 issues with storage where previously we didn't have to store  
5 the drug a certain way. Now there were new storage  
6 instructions such as refrigeration.

7 Q. The refrigeration instruction came at the time that  
8 the Vasopressin initially became a brand drug; right?

9 A. Yes. I'm not sure exactly whether that happened. I  
10 just associate Vasopressin coming out with these new  
11 refrigeration requirements.

12 Q. Okay. And you don't know whether those were as a  
13 result of the reformulation or were applied to original  
14 Vasopressin when it was first sold; right?

15 A. I don't know.

16 Q. And since Vasopressin was introduced by a branded  
17 product, you have not seen any changes in your practice in  
18 the way that it's used; right?

19 A. Besides the refrigeration issue, that's correct. Also  
20 depending how long back in time we go, earlier, there was an  
21 indication for use of vasopressin where we gave it  
22 differently. Instead of an IV drip, we gave it as an IV  
23 push during cardiac arrest. That was more of a clinical  
24 change that happened I think independent of the Vasopressin  
25 branding.

Colaric - cross

1 Q. Right. That wasn't a change that arose as a result of  
2 the Par's introduction of Vasostrict?

3 A. Correct.

4 Q. And in talking about the original Vasostrict when it  
5 was first approved, you're not aware there were any safety  
6 issues with the original Vasostrict product?

7 A. Generally speaking, not aware.

8 Q. For example, there wasn't any recall of original  
9 Vasostrict, was there?

10 A. Not that I can recall.

11 Q. And you're not aware of any issue with the amount of  
12 impurities that was in the original branded Vasostrict  
13 product; is that right?

14 A. I'm not aware of that.

15 Q. And now as long as -- well, you testified during your  
16 direct that physicians are not testing formulations for pH;  
17 right?

18 A. Correct.

19 Q. And so as long as it meets the FDA approved  
20 specification, physicians wouldn't care what the pH was it;  
21 right?

22 A. Yes. Physicians, pharmacists, we will use whatever is  
23 provided within that vial.

24 Q. Sure. The same with impurities. As long as a vial  
25 meets the impurities limitation that the FDA has set out,



Colaric - cross

1 pharmacists won't care the specific amounts of impurities in  
2 a vial; right?

3 A. One thing from clinical practice I can tell you is  
4 that we do examine each vial and each drip before we send it  
5 to the patient. If there's something visible in there  
6 that's precipitating, I'm not sure that's an impurity or  
7 not, but that would be a hard stop for us not to dispense  
8 that medication. But other than that, we're not going to be  
9 chemically testing the drug before we send it out.

10 Q. Okay. And with respect to the specific amounts of  
11 particular impurities, a physician is not going to know how  
12 many are in any individual vial of vasopressin. Right?

13 A. Correct.

14 Q. And the physicians would also assume that if the  
15 specifications for impurities are met, the product is going  
16 to be safe to give to patients; right?

17 A. I mean, generally speaking, physicians, pharmacists,  
18 nurses, once we get the drug from the manufacturer and we  
19 use it in a way that they tell us how to use it, we would  
20 expect it to be safe.

21 Q. Let's talk a little bit about how Eagle's product  
22 likely are to be used. On direct you discussed the shelf  
23 life of Eagle's product and you mentioned that they're  
24 proposing a 24-month refrigerated with 12 months out of  
25 refrigeration; right?

Colaric - redirect

1 A. Correct.

2 Q. And so at the 24-month period for manufacture, that  
3 batch will expire no matter how it's stored; right? Be  
4 expired?

5 A. Correct. Clinically, I won't be able to use that drug  
6 once that date expires.

7 Q. That was going to be my next question. Once the  
8 product expires, clinically, you can't use that product?

9 A. That's right.

10 Q. And you aren't suggesting that Eagle is instructing  
11 physicians to use their product after the 24-month expiry;  
12 right?

13 A. No, I'm not saying that.

14 MR. LASKY: I have no further questions.

15 THE COURT: Thank you. Any redirect?

16 MR. Rhoad: Yes, Your Honor. Just a couple  
17 quick questions.

18 REDIRECT EXAMINATION

19 BY MR. RHOAD:

20 Q. Dr. Coralic, do you as a clinician know what the FDA  
21 specifications for release or stability of the drug products  
22 that you administer are?

23 A. As a clinician, I don't deal with that.

24 Q. And do you have any way to test the product to see  
25 whether it meets those specifications?

1 A. Other than basically inspecting the drug before I  
2 dispense it, we don't do any chemical analysis.

3 Q. So you just rely on the fact that it's an FDA approved  
4 drug and you store it in the way you're supposed to store  
5 it?

6 A. Correct.

7 MR. RHOAD: No further questions. Thank you.

8 THE COURT: Thank you very much. You're  
9 excused.

10 (Witness excused.)

11 THE COURT: Mr. Black?

12 MR. BLACK: Thank you, Your Honor. At this time  
13 we will call by deposition Ronald Aungst. He's an AMRI  
14 employee. They're the manufacturer. We have a short  
15 deposition clip relating to the information discovered  
16 between the trial and today.

17 THE COURT: Okay.

18 MR. BLACK: We'll play that.

19 THE COURT: Do you all have a transcript of  
20 that?

21 MR. BLACK: Your Honor, a small point of  
22 clarification. They have some designations from the earlier  
23 deposition of Dr. Aungst that they would like to play in  
24 their case. We're going to play them together because it's  
25 one witness even though it's two depositions to accommodate

1       them, but that's not evidence in our case, it's evidence in  
2       their case.

3               THE COURT:   Okay.

4               MR. BLACK:   Or we can wait.

5               THE COURT:   No.   I think, you know, I heard some  
6       invalidity questions that were asked of your witness, you  
7       know.   Let's just do it all at once.

8               MR. BLACK:   So we'll proceed then with playing  
9       the clip of Dr. Aungst.

10              THE COURT:   You all agreed to it.   Right?

11              MR. BLACK:   Yes, we're fine.

12              THE COURT:   It sounds good.

13              MR. LASKY:   To be clear, Your Honor, they're  
14       playing the later deposition before the early one.   We don't  
15       object, but for context.

16              THE COURT:   Okay.   All right.   And, look.   I  
17       don't mind.   It's your time.   If you thought later on you  
18       want to replay some further expert in your case because it  
19       made sense, that's fine with me, too.   You all figure out  
20       how you want to use your time.   So that sounds good.

21              MR. GOLDBERG:   Your Honor, my name is Brian  
22       Goldberg.   I'm from Dechert.

23              The Par portion of this first clip, the 2021  
24       deposition is 18 minutes, two seconds, and Eagle's, three  
25       minutes and 49 seconds.   Then we'll move in some exhibits

Aungst - designations

1 once the testimony is done.

2 THE COURT: Okay. Hold on a second. Okay.

3 Thank you. Actually, hold on a second. The transcript.

4 MR. KWON: Your Honor, this is for defendant.

5 For the 2019 clip that will be following, for context,  
6 defendants' designations are the total time of the clip is  
7 25 minutes.

8 THE COURT: Okay.

9 MR. KWON: For the second clip that will be  
10 following plaintiffs' clip.

11 THE COURT: All right. Is your transcript part  
12 of this or is it a separate transcript?

13 MR. KWON: It's a separate transcript, Your  
14 Honor.

15 THE COURT: Let's play the 18, see where we are.  
16 I will ask maybe for the second transcript.

17 And your name, please?

18 MR. KWON: Sam Kwon, Your Honor.

19 THE COURT: Thank you. Okay.

20 (The videotaped deposition of Ronald Aungst was  
21 played as follows.)

22 ...RONALD AUNGST, Ph.D., after having been first  
23 duly sworn, was examined and testified as follows...

24 "Question: Good morning, Dr. Aungst. How are  
25 you?

Aungst - designations

1 "Answer: I'm good.

2 "Question: Thank you for being here. Can you  
3 state your full name for the record?

4 "Answer: Yes. It's Ronald Allen Aungst, Jr.

5 "Question: I have introduced Exhibit 1 to this  
6 deposition, which is Par's notice of 30(b)(6) deposition to  
7 Eagle pharmaceuticals.

8 "Answer: Yes.

9 "Question: Do you see that?

10 "Answer: I do see it.

11 "Question: Have you seen this notice before?

12 "Answer: I have.

13 "Question: And you understand that you've been  
14 designated to testify on behalf of Eagle, AMRI and Oso  
15 regarding topics 1, 2, 3, 4, 5 and 7?

16 "Answer. Yes.

17 "Question: And you understand that your answers  
18 are on behalf of Eagle, AMRI and Oso then?

19 "Answer: I do.

20 "Question: You are currently employed by AMRI;  
21 is that right?

22 "Answer: I am.

23 "Question: Is your title senior director of  
24 global program management?

25 "Answer: Correct.

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1 "Question: How many batches has AMRI made for  
2 Eagle since SVA 009?

3 "Answer: We would have batches SVA 010 through  
4 SVA 017, so a total of seven batches.

5 "Question: And AMRI manufactured batches SVA11  
6 through 13 for Eagle, right?

7 "Answer: Correct.

8 "Question: Why did Eagle make batches SVA11  
9 through 13?

10 "Answer: Those are the performance -- process  
11 performance qualification batches.

12 "Question. Do batches SVA11 through 13 also  
13 intend to be commercial batches?

14 "Answer: Their potential -- their potential is  
15 for use in the regulatory filings as well as if approved,  
16 then Eagle could utilize those.

17 "Question: So if it approved, Eagle could sell  
18 those batches?

19 "Answer: Yes.

20 "Question: Okay. I just introduced Exhibit 2  
21 to this deposition, which is a document with the Bates stamp  
22 AMRIVAS0118363. And this is tab 13 in your binder if you  
23 want to look at it there.

24 Answer: I have it pulled up.

25 "Question: Do you recognize Exhibit 2?

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1 "Answer: I do.

2 "Question: What is it?

3 "Answer: It's the PPQ protocol associated  
4 with -- looks like lot 11 of SVA.

5 "Question: Are the -- are the PPQ protocols the  
6 same for batches SVA 12 and 13 as well?

7 "Answer: Let me flip through this entire thing  
8 here again. Yes. In fact, I think this is not only for  
9 SVA11, it's also inclusive of SVA12 and 13.

10 "Question: I think we talked about it a little  
11 bit earlier, but can you explain what process performance  
12 qualification is?

13 "Answer: Sure. We are looking to validate  
14 the overall process to show that we are in full control of  
15 our process and will continue to provide or manufacture  
16 product that meets the requirements to suit the -- the label  
17 claims.

18 "So what you do is you will need to test various  
19 portions of the batch manufacture that are not typically  
20 tested on a routine basis, but in order to ensure that each  
21 of those understandings and modifications that occurred  
22 during a process potentially can be understood.

23 "So you're looking for critical process  
24 parameters and to assure that the critical quality  
25 attributes are maintained.



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1 "Question: Returning to the page  
2 AMRIVAS0118387, this is the validation procedures portion of  
3 the PPQ protocol.

4 "Answer: Okay. I'm there.

5 "Question: This is the validation procedure  
6 portion of the PPQ protocol?

7 "Answer: Yes.

8 "Question: And there were four test functions  
9 run as part of the PPQ protocol; is that right?

10 "Answer: That's accurate.

11 "Question: Turning to the page AMRIVAS118399,  
12 this is the portion of the PPQ protocol that describes test  
13 function three; is that right?

14 "Answer: Yes, that is correct.

15 "Question: And under the objective, it says,  
16 the objective of this test is to verify the uniformity of  
17 the SVA finished product and ensure it meets the final  
18 product specifications over the entire fill.

19 "Answer: Yes.

20 "Question: So am I right that what the  
21 objective is referring to, when it says 'the entire fill,'  
22 is the process of taking the bulk solution and filling it  
23 into the final packaging of the product?

24 "Answer: That is correct, yes.

25 "Question: It also says that, 'The objective of

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1 the test is to verify the uniformity of the SVA finish over  
2 the entire fill.

3 "Answer: Yes.

4 "Question: What does -- what does that mean?

5 "Answer: It means a -- the content uniformity  
6 of the batch is not impacted by the length of the run. So  
7 you're getting consistent results across the entire batch.  
8 So you test beginning -- beginning samples, middle samples,  
9 and end samples to verify that.

10 "Question: So am I right that the purpose of  
11 test function three was to make sure that the attributes of  
12 the drug product are consistent across the entire length of  
13 the fill?

14 "Answer: Yes, that is correct.

15 "Question: So you want the drug product from  
16 the vials filled at the beginning of the filling process to  
17 have the same attributes as the vials that are filled at the  
18 end of the filling process; is that right?

19 "Answer: Yes.

20 "Question: You mentioned that the vials were  
21 segregated into vials filled from the beginning of the  
22 filling process, middle of filling process, and end of the  
23 filling process?

24 "Answer: Correct.

25 "Question: And vials from the beginning,

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1 middle, and end were all tested for pH?

2 "Answer: That is correct, for each batch.

3 "Question: I see in the last column of table 12  
4 under 'Samples,' do you see that column?

5 "Answer: Yup.

6 "Question: And it says, non-routine, 90B, 90M,  
7 90E?

8 "Answer: Correct.

9 "Question: So does that mean there were 90  
10 beginning of the filling process vials, 90 of the middle  
11 filling process vials, and 90 of the end of the filling  
12 process vials used for this testing?

13 "Answer: That means that 90 -- 90 -- excuse  
14 me -- 90 vials from the beginning, 90 vials from the middle,  
15 and 90 vials from the end were pulled for use in doing this  
16 testing, yes.

17 "Question: So with respect to pH for SVA11, the  
18 release pH was determined by using the values that were  
19 measured from test function number three of the PPQ  
20 protocol?

21 "Answer: That is correct.

22 "Question: And that pH testing involved testing  
23 beginning vials, middle vials, and end vials; is that right?

24 "Answer: That is correct.

25 "Question: And going forward, there won't be pH

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1 tests for release on beginning, middle, and end vials;  
2 right? There will just be one test?

3 "Answer: It will be a test based upon random  
4 sampling of the entire batch.

5 "Question: So there won't be three separate  
6 tests? There will just be one test with random sampling of  
7 the -- of the batch?

8 "Answer: That would be the intent, yes. It  
9 doesn't mean that will be the only number of tests that are  
10 run. It just is what the intent will be. It all depends  
11 upon the needs of the -- of the batch.

12 "Question: I just introduced Exhibit 3, which  
13 is a document with a Bates stamp AMRIVAS0118020.

14 "Answer: Yes. I have it up.

15 "Question: Do you recognize Exhibit 3?

16 "Answer: I do.

17 "Question: What is it?

18 "Answer: This is the lab notebook page where  
19 they recorded the pH results of SVA011 beginning, middle,  
20 and end.

21 "Question: Okay. So the pH testing that's  
22 listed here, that's the test function number three pH  
23 testing ?

24 "Answer: That is.

25 "Question: So for the vials from the beginning

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1 of the filling process, Ms. Smith recorded a pH of 3.54?

2 "Answer: Correct.

3 "Question: And then that got reported as 3.5?

4 "Answer: Correct.

5 "Question: That's just because of normal  
6 rounding; is that right?

7 "Answer: That is accurate.

8 "Question: And then for the vials filled from  
9 the middle of the filling process, Ms. Smith recorded a  
10 value of 3.56?

11 "Answer: Correct.

12 "Question: And that was reported as 3.6?

13 "Answer: Correct.

14 "Question: And then the vials at the end of the  
15 filling process, Ms. Smith recorded a pH of 3.57?

16 "Answer: Correct.

17 "Question: And that was reported as 3.6?

18 "Answer: Correct.

19 "Question: And then Ms. Smith averaged the  
20 three values, which came out to 3.56?

21 "Answer: Correct.

22 "Question: And that was reported as 3.6?

23 "Answer: Correct.

24 "Question: And it's your understanding that  
25 that average value, the 3.6, was supposed to serve as the

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1 release pH for batch SVA11?

2 "Answer: Based on this testing, correct.

3 "Question: And there's a reviewer also at the  
4 bottom of the page, the initials REF. Do you see that?

5 "Answer: I do.

6 "Question: What's the purpose of having someone  
7 initial the bottom of each lab notebook page?

8 "Answer: To indicate that the overall lab  
9 notebook was documented correctly and also the tests were  
10 run accurately.

11 "Question: Now, there had been some inadvertent  
12 additional pH testing conducted on SVA11 in the PPQ  
13 protocol, right?

14 "Answer: Yes, I understood that.

15 "Question: I'm marking Exhibit 6, which is a  
16 document with the Bates stamp AMRIVAS0120355, and this is  
17 tab 18 in your binder. It's taking a second to load on  
18 Exhibit share. I apologize for that.

19 "Answer: Yeah. I was just going to ask.

20 "Question: Do you recognize Exhibit 6?

21 "Answer: I do.

22 "Question: What is it?

23 "Answer: It's the lab notebook for the PPQ  
24 protocol analysis.

25 "Question: Turning to the last page of

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1 Exhibit 6, which is is AMRIVAS0120364. Can you let me know  
2 when you're there?

3 "Answer: Okay. I'm here.

4 "Question: So this is the pH data that was run  
5 per test function number three in the SVA11 PPQ protocol  
6 notebook?

7 "Answer: Correct.

8 "Question: And this pH testing was conducted on  
9 December 2nd, 2020?

10 "Answer: Correct.

11 "Question: And Tania Espina conducted this pH  
12 testing?

13 "Answer: Correct.

14 "Question: And it was reviewed; is that right?

15 "Answer: It's reviewed. I don't know who it's  
16 reviewed by, though.

17 "Question: And Ms. Espina, is she another  
18 employee within the chemistry group at the OSO facility in  
19 Albuquerque, New Mexico?

20 "Answer: Yes.

21 "Question: And for the beginning vials, Ms.  
22 Espina tested the pH and recorded a pH of 3.51?

23 "Answer: Correct.

24 "Question: And for the middle vials, Ms. Espina  
25 tested the pH and recorded a pH of 3.49?

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1 "Answer: Correct.

2 "Question: And for the end vials, Ms. Espina  
3 recorded a pH of 3.47?

4 "Answer: Correct.

5 "Question: The December 2nd pH test, those were  
6 the ones that were conducted in error; is that right?

7 "Answer: They were the second set that was  
8 generated. So I believe those would be the ones that were  
9 conducted in error.

10 "Question: I just introduced Exhibit 7, which  
11 is a document with the Bates stamp AMRIVAS0120365. This is  
12 tab 19 in your binder.

13 "Answer: Okay. I have it up.

14 "Question: Do you recognize Exhibit 7?

15 "Answer: Yes.

16 "Question: What is it?

17 "Answer: It's the same notebook page as  
18 Exhibit 6, just dated in the later time frame.

19 "Question: So the first page of Exhibit 7 is  
20 the lab notebook page from the SVA11 PPQ protocol that  
21 recorded the pH testing?

22 "Answer: That's right. The first page is.

23 "Question: And the second page is the page from  
24 the SVA11 end product lab notebook that recorded the pH  
25 testing?



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1 "Answer: Correct.

2 "Question: So what happened once this issue was  
3 discovered?

4 "Answer: Well, it was determined, since we have  
5 a, you know, our SOP and the documentation practice requires  
6 us to maintain all the valid data, just this data was  
7 collected on the beginning, middle, and end per the protocol  
8 for TF -- test function number three for SVA11. We had no  
9 reason to not utilize all six values because all values were  
10 identified as valid -- valid values.

11 "Question: Can you remind me what Derrick  
12 Yazzie's title is?

13 "Answer: He's the QC chemistry manager  
14 question.

15 "Question: And do you know when Mr. Rael  
16 identified the second set of testing?

17 "Answer: Yeah. Derrick indicated that it was  
18 late January. He didn't have a precise date either, very  
19 similar to what I noted. I knew it was late January, and  
20 that's what he recalled as well.

21 "Question: And do you know who Robert Rael  
22 informed within AMRI that he had discovered the second set  
23 of testing?

24 "Answer: So I informed Derrick, in particular,  
25 and Derrick is the one that made the decision to go forward

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1 with, you know, including that testing in the overall  
2 substance for putting together the end product testing  
3 value.

4 "Question: And do you know if Eagle provided  
5 any input into how to report the SVA11 pH data?

6 "Answer: Yeah. Derrick confirmed that this was  
7 solely his -- his decision. You know, this is an AMRI  
8 quality system driven decision through our SOP's. So he --  
9 he made that decision all on his own.

10 "Question: Okay. So let me just make sure I  
11 understand.

12 "On November 30th 2020, Tamara Smith conducted  
13 pH testing on batch SVA11 per the test function three of the  
14 PPQ protocol, right?

15 "Answer: That's correct.

16 "Question: And on December 2nd, the test  
17 function three pH testing was inadvertently repeated by  
18 Tania Espina?

19 "Answer: Correct.

20 "Question: And this issue of duplicate pH  
21 testing being conducted was discovered by Robert Rael in  
22 gathering documents for production in this litigation,  
23 sometime in the end of January 2021?

24 "Answer: That is what we understood, yes.

25 "Question: And your understanding is that he

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1 then told Derrick Yazzie about the duplicate pH testing?

2 "Answer: That's correct.

3 "Question: And then Derrick Yazzie on his own  
4 made the decision on how to report the pH data?

5 "Answer: That's correct.

6 "Question: And Mr. Yazzie's decision was to  
7 report all six pH results?

8 "Answer: It was.

9 "Question: And do you know why he made that  
10 decision?

11 "Answer: Because all test results were  
12 considered valid test results. We had no indication that  
13 any of the other -- any results were not valid. So per our  
14 SOP, we maintain all data and utilize that data for the  
15 overall results.

16 "Question: And what do you mean by valid test  
17 results?

18 "Answer: We had no indication that either the  
19 first set nor the second set were invalid, i.e., they had  
20 a -- a lab error or anything of that nature. All  
21 indications were they were accurate results. So we utilized  
22 all data.

23 "Question: So with respect to the end product  
24 lab notebook that we reviewed earlier, that lab notebook  
25 page is now going to list all six of the pH measurements

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1 that were recorded for SVA11?

2 "Answer: That's correct.

3 "Question: And for the end product data  
4 collection form, it's going to report one pH value which is  
5 an average of all six pH measurements that were taken for  
6 SVA11?

7 "Answer: For the end product, yes.

8 "Question: And for the PPQ data collection  
9 form, that is going to be revised some time soon to list all  
10 six of the pH measurements that were taken on SVA11?

11 "Answer: That would be correct, yes. That's a  
12 decision being taken by quality assurance.

13 "Question: Okay. And you're not aware of any  
14 input from Eagle with respect to how this data is going to  
15 be reported, as we just discussed?

16 "Answer: No.

17 "Question: And there were no alternatives  
18 considered for the end product data collection form?

19 "Answer: No.

20 "Mr. Goldberg: I also have introduced  
21 Exhibit 17, which is a document with the Bates stamp  
22 AMRIVAS0120375. And that's tab 12 in your binder?

23 "Answer: Yup, I have it updated.

24 "Question: And do you recognize Exhibit 17?

25 "Answer: Yes.

1 "Question: And what is Exhibit 17?

2 "Answer: It's an updated C of A for the in  
3 process -- in process testing of SVA011."

4 (End of videotaped deposition.)

5 MR. GOLDBERG: With Your Honor's permission, Par  
6 would move into evidence PTX-1217, PTX-1235, PTX-1321,  
7 PTX-1344 and PTX-1353 from the testimony of Dr. Angst.

8 And I believe from the next clip that's going to  
9 be played --

10 THE COURT: Hold on. First of all, do you have  
11 any objection?

12 MR. KWON: No objections, Your Honor.

13 THE COURT: Before I admit them, why is PTX-1353  
14 relevant?

15 MR. GOLDBERG: Your Honor, it's the in process  
16 certificate of analysis from batch SVA11. It's one of the  
17 data points you saw on the board that Mr. Hales was  
18 discussing. It's going to be discussed later with our  
19 expert in their subsequent testimony.

20 THE COURT: All right. Well, I'm going to admit  
21 everything, but I'm going to admit that conditionally on  
22 there's some discussion about it.

23 MR. GOLDBERG: Yes, Your Honor.

24 MR. KWON: Thank you, Your Honor.

25 (PTX-1217, PTX-1235, PTX-1321, PTX-1344 and

1 PTX-1353 were admitted into evidence.)

2 MR. GOLDBERG: Your Honor, from the next clip,  
3 ten minutes and 51 seconds is allotted to Par.

4 THE COURT: Okay. So hold up. Did you read the  
5 total time or did you read just Eagle's time or defendants'  
6 time? How did you do that?

7 MR. KWON: Your Honor's Eagle's time is  
8 14 minutes and 16 seconds.

9 THE COURT: Okay. You've got ten?

10 MR. GOLDBERG: Ten minutes, 51 seconds, Your  
11 Honor.

12 THE COURT: All right. Let's talk about time  
13 and lunch because this is so riveting. I don't know why you  
14 guys don't call live witnesses if you can avoid the  
15 depositions. I mean, break for lunch? How much time do you  
16 need?

17 MR. BLACK: Really how much time you'll allow  
18 us, Your Honor.

19 THE COURT: Well, half-an-hour? Do you have a  
20 sandwich brought to the building?

21 MR. BLACK: We do.

22 THE COURT: Do you want to break for  
23 half-an-hour?

24 MR. BLACK: We're under Mr. Farnan's auspices  
25 here, so we can do half-an-hour.

1 MR. HALES: We're fine with that, too.

2 MS. WU: Yes.

3 THE COURT: Okay. We'll plan on about  
4 half-an-hour. Actually then, let's break now. We'll come  
5 back at 1:00 o'clock and we'll plan on starting up with the  
6 deposition that we're going to play.

7 MR. BLACK: Thank you, Your Honor.

8 THE COURT: All right. Thank you, all.

9 (Luncheon recess taken.)

10 - - -

11 Afternoon Session, 1:03 p.m.

12 THE COURT: Please be seated. Who is next?

13 MR. BLACK: You said you wanted to take a  
14 deposition designation objection.

15 THE COURT: Yes.

16 MR. BLACK: At lunch. I can do that now.  
17 There's one quick issue.

18 THE COURT: Does it deal with the one we're  
19 about to play?

20 MR. BLACK: It does not deal with the one we're  
21 about to play. We can do it now or after we finish Aungst.  
22 Either way.

23 THE COURT: It has to be covered tomorrow. Why  
24 don't we go ahead. While people are prepping, I can  
25 entertain it. So, in other words, you're going to have to

1 cut the film today. Let's go ahead.

2 MR. BLACK: It relates to Mr. Kenesky, and if I  
3 can just hand up --

4 THE COURT: And this is the in-house -- not the  
5 in-house. The Wilson Sonsini associate?

6 MR. BLACK: Yes.

7 THE COURT: Yes.

8 MR. BLACK: Let me just hand up the materials.  
9 The defendants would like to play, for instance, page 153,  
10 lines through to 11.

11 THE COURT: Okay.

12 MR. BLACK: Which says, Mr. Kenesky, objection.  
13 I instruct the witness not to answer. Calls for  
14 attorney/client communication and there's no answer. They  
15 want to play that.

16 They want to play a series of --

17 THE COURT: All right. Let's do it line --  
18 actually, go ahead. Lay out everything you're going to play  
19 and then we'll address them line by line. Okay? That's one  
20 thing they want to play. So 153, lines 3 through 11. They  
21 said they want to play that?

22 MR. BLACK: They said they said they want to  
23 play that and there are a couple of others like that where  
24 there is an answer to the question and an objection and no  
25 answer and that's not appropriate.



1 THE COURT: All right. Mr. Hales?

2 MR. HALES: Yes, Your Honor.

3 THE COURT: You're going to risk your client on  
4 this line 3 through 12? Go ahead. I'm serious. There's an  
5 attorney/client privilege communication objection and no  
6 answer and you want to play it?

7 MR. HALES: Here's the issue. What is important  
8 for Your Honor to understand relates to different than what  
9 we argued about in January, but Mr. Kenesky is not going to  
10 be here. We asked a question. They instructed not to  
11 answer, and therefore what they can't do is argue to Your  
12 Honor some inference or, you know, we asked questions about  
13 did you do an investigation, did you believe what Mr.  
14 Kannan put in the declaration. They instructed him not to  
15 answer. Whether right or wrong, they instructed him not to  
16 answer, so there was no discovery on that.

17 All we're saying is they can't come in and try  
18 to argue -- they are not going to bring him in Mr. Black has  
19 said, but they can't try to argue any inference or he didn't  
20 know or didn't realize.

21 THE COURT: Wait. Who is the they?

22 MR. HALES: Mr. Kenesky, the attorney. So the  
23 point is, Your Honor needs to know what the scope is where  
24 they can't argue or try to that infer that what Mr. Kenesky  
25 said was okay when it was on the specific question that they

1 asked that we didn't get any discovery of. That would be  
2 addressed in briefing for an appropriate way.

3 THE COURT: Just this question?

4 MR. BLACK: There are several like this, Your  
5 Honor.

6 THE COURT: Where there's a privilege objection?

7 MR. BLACK: Privilege objection. No answer,  
8 they want to read it. What's going on here, they're  
9 attacking this associate from Wilson Sonsini. We took the  
10 privilege as we're entitled to do and it's their burden on  
11 clear and convincing evidence and we don't have to choose  
12 between waiving privilege and having an inference against  
13 them.

14 Second --

15 THE COURT: Whoa.

16 MR. BLACK: That's an issue for later.

17 THE COURT: No. Hold on. So are you going to  
18 be calling Kenesky?

19 MR. BLACK: No.

20 THE COURT: Are you going to be playing the  
21 deposition testimony from Kenesky?

22 MR. BLACK: Whatever we're playing is going to  
23 be cross-designated and that's all agreed. These specific  
24 questions are the problem.

25 THE COURT: Are you playing Kenesky's testimony

1 in which Kenesky waived the privilege?

2 MR. BLACK: No.

3 THE COURT: Okay. So, Mr. Hales, they didn't  
4 waive the privilege. So give me a specific example you  
5 think they're going to be arguing.

6 MR. HALES: So I will just use this one. So did  
7 Mr. Kannan before he signed the declaration tell you what  
8 Mr. Kenney's contribution was? Instruction not to answer.

9 So I just don't want to have any inference  
10 argued by them about --

11 THE COURT: Well, what's the inference? So far  
12 I have not heard anything. They are not waiving the  
13 privilege.

14 MR. HALES: No. Somehow or another they're  
15 going to argue it was all innocent. They're going to say  
16 Mr. Kannan was mistaken about what the declaration was.  
17 They're going to argue that Mr. Kenesky had no idea, he had  
18 no way of knowing that.

19 THE COURT: Why don't we wait and see what they  
20 argue and then you can, if you think that they've waived or  
21 they've implicated, then maybe I will entertain it. But I  
22 will entertain whether you could play this or not, but I  
23 mean, they'd have to open the door. Otherwise, this is not  
24 admissible. It's like putting a defendant in a criminal  
25 case on so they can invoke the Fifth in front of the jury.

1 They don't get to do that.

2 MR. HALES: All we're saying is the other  
3 example, they're saying Mr. Kannan, this is one of the other  
4 questions.

5 THE COURT: So I'm not allowing this to be  
6 played. Don't put in the deposition.

7 MR. BLACK: There are a couple others like that.  
8 We'll can sort out which are the same. The next page, 167,  
9 this is the opposite problem. This is the question he put  
10 up in the opening.

11 Did you during the '239 patent prosecution in  
12 fact know that Mr. Kenney, blah, blah, blah.

13 And there was an objection by the Wilson Sonsini  
14 partner. Assumes facts -- correct. It assumes a fact  
15 that's not in evidence. It's argumentative. It does  
16 implicate --

17 THE COURT: I will sustain the objection.

18 MR. BLACK: All right. Thank you, Your Honor.

19 THE COURT: I mean, if you want to be heard for  
20 the record, go ahead.

21 MR. HALES: Well, he does not know what he did  
22 or didn't know. I think it's appropriate for the Court to  
23 know that.

24 THE COURT: Yes. I think the question is a  
25 loaded question. It assumes facts that aren't in evidence.

1 It would mislead a fact-finder, and for that reason I would  
2 preclude it being admitted under Rule 402, 403, or 403,  
3 rather. I think it lacks clarity. There are all sorts of  
4 problems with the question and so I'm going to sustain the  
5 objection.

6 MR. BLACK: Thank you, Your Honor. Those two  
7 rulings will allow us to resolve the others in here in  
8 similar fashion. If anything else comes up, we'll get back  
9 to you.

10 THE COURT: Okay.

11 MR. BLACK: Thank you. So we'll return to the  
12 deposition of Dr. Aungst. This will be his second  
13 deposition, 2019. I believe Mr. Goldberg is --

14 MR. GOLDBERG: This is what Eagle would like to  
15 play.

16 THE COURT: This is Eagle's clip. You sorted it  
17 out, ten and 14 I think respectively. Ten minutes for you,  
18 14 for them.

19 MR. BLACK: That's correct.

20 THE COURT: All right.

21 MR. HALES: Time out. I don't think I have the  
22 transcript. May I?

23 THE COURT: Thank you. Okay. So we can go  
24 ahead then. Thank you very much.

25 MR. HALES: Your Honor, the way we put these

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1 together, the exhibits are going to be shown alongside it.  
2 It's not in that package you have, but we can get you one.

3 THE COURT: That's fine.

4 (The videotaped deposition of Ronald Aungst was  
5 played as follows.)

6 "Question: So can you give me your full name?

7 "Answer: Yes, Ronald Aungst, Jr.

8 "Question: Why did AMRI decide to use VASO1 as  
9 the RLD for the Eagle ANDA product?

10 "Answer: That was the RLD that was available in  
11 the market when we purchased.

12 "Question: There was no other VASO product  
13 available on the market?

14 "Answer: Not that we had identified.

15 "Question: Are you currently employed by AMRI?

16 "Answer: I am.

17 "Question: How long have you been employed by  
18 AMRI?

19 "Answer: Nearly 18 years.

20 "Question: What's your current job title?

21 "Answer: Senior director, global program  
22 management.

23 "Question: If the FDA approves Eagle's ANDA,  
24 what will AMRI's role be?

25 "Answer: We will be the manufacturer of the

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1 product.

2 "Question: Anything else?

3 "Answer: We are partners but we are not doing  
4 any of the marketing. That was Eagle's role, so we do the  
5 manufacture and transfer the product to Eagle and they will  
6 do the subsequent sale of the product.

7 "Question: And if a product is outside of those  
8 release specs, AMRI would not release it to Eagle; right?

9 "Answer: Outside of the release specs, there  
10 would be a deviation opened up and there will be a  
11 discussion at the quality level between the two parties on  
12 how that is handled.

13 "Question: But the product would not go from  
14 AMRI to Eagle to be sold to customers; right?

15 "Answer: Not without a fully dispositioned  
16 release batch, not unless it's a fully dispositioned release  
17 batch.

18 "Question: What is a fully dispositioned  
19 release batch?

20 "Answer: The quality terms that would require  
21 AMRI to release the batch and be fully dispositioned, so it  
22 basically meets criteria specs that are necessary.

23 "Question: So I don't think I understand what  
24 you mean by dispositioned. What do you mean by  
25 dispositioned?

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1                   "Answer: Dispositioned means you've gone  
2 through the batch records, you've completed all your  
3 investigations necessary to close any deviations that may  
4 have occurred along the way, and if there's any out of spec,  
5 that those investigations have been executed to confirm  
6 whether or not the product is ready for release.

7                   "So when it's ready for release, we do what's  
8 called a dispositioning, which is basically closing out all  
9 the documents and QA sign-off. That's disposition, or  
10 release. Just difference in terminology, that's all.

11                  "Question: So are you saying that AMRI could  
12 potentially release a product to Eagle for sale that does  
13 not fall within AMRI's release specifications?

14                  "Answer: No, I'm not saying that.

15                  "Question: Can you just explain that?

16                  "Answer: What I'm saying is if there is a  
17 release spec that is not met initially, there will be a  
18 discussion between AMRI's quality and Eagle's quality to  
19 determine the path forward on whether or not this batch  
20 could be dispositioned.

21                  "That determination could lead to an  
22 investigation which could either reinforce the fact that  
23 there is no list or it could identify that there was an  
24 issue associated with the actual testing and the test would  
25 be redone.



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1 "So that investigation needs to occur first. So  
2 that's kind of a stop gap that needs to occur before  
3 anything can happen for that batch to be released. At that  
4 point in time it is in quarantine and cannot be released.  
5 So depending on the outcome of the investigation and the  
6 result, then the batch could be or could not be released.  
7 It all depends on the result.

8 "Question: So if the investigation shows that  
9 the batch is actually within the release spec, then it could  
10 be released?

11 "Answer: It could be released.

12 "Question: But if the investigation shows that  
13 the batch remains out of spec, it would not be released to  
14 Eagle?

15 "Answer: Correct.

16 "Question. When OSO manufactures commercial  
17 batches, what will they be relying on for direction as to  
18 how to make those commercial batches?

19 "Answer: The most updated proposed commercial  
20 batches that were put together jointly between AMRI and  
21 Albuquerque and Eagle Pharmaceuticals.

22 "Question: Can you turn back to Exhibit 3? Do  
23 you have it?

24 "Answer: Yes.

25 "Question: Do you recognize this document?

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1 "Answer: Yes.

2 "Question: This is a module 1.12.11 basis for  
3 submission; right?

4 "Answer: Yes.

5 "Question: And under heading three, if you look  
6 at the last paragraph on that page, second line down, it  
7 says, FDA determined that Eagle's formulation and the  
8 originally approved Vasostrict formulation qualitatively and  
9 quantitatively equivalent as documented in controlled  
10 correspondence 9350150.

11 "Do you see that?

12 "Answer: Yes.

13 "Question: What does qualitatively and  
14 quantitatively equivalent mean?

15 "Answer: They have the identical amounts and  
16 types of excipients and API in the vial.

17 "Question: And what is the significance of a  
18 drug --

19 "Answer: Bioequivalent.

20 "Question: You mention there was a CRL; right?

21 "Answer: Correct.

22 "Question: Has the formulation of Eagle's ANDA  
23 changed in response to that CRL?

24 "Answer: The formulation of the product has not  
25 changed. The process to manufacture has been slightly

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1 modified.

2 "Question: This is Exhibit 14. Do you  
3 recognize this document?

4 "Answer: Yes. This is the pharmaceutical  
5 development report.

6 "Question: And what are exhibit batches?

7 "Answer: They are batches that are used to put  
8 on stability, evaluate stability of the product and its  
9 content versus what the RLD would be and utilized ultimately  
10 in the filings as the data points.

11 "Question: Is exhibit batches the same as  
12 registration batches?

13 "Answer: Yes.

14 "Question. Can you turn to the page that ends  
15 in Bates No. 12150, which is the next page?

16 "Do you see the last three rows of Table 1,  
17 SVA001, SVA002, SVA003.

18 "Answer: Yes.

19 "Question: And those are the three exhibit  
20 batches?

21 "Answer: They are.

22 "Question: Are these exhibit batches  
23 representative of what Eagle will sell commercially upon FDA  
24 approval?

25 "Answer: They are representative of the process

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1 that was utilized for the registration. However, the  
2 process has changed and there will be some slight  
3 modifications that ultimately will probably result in some  
4 slight changes in terms of the pH within the overall product  
5 at the time of release.

6 "Question: Are they representative of the  
7 formulation?

8 "Answer: Yeah, absolutely, still within the  
9 spec. Just tightening up the process.

10 "Question: If AMRI and Eagle release a batch,  
11 it will do so upon looking at the release specs?

12 "Answer: Not exclusively, no.

13 "Question: At least in part, it will look at  
14 the release specs in order to determine whether to release  
15 that product, right?

16 "Answer: In part, yes.

17 "Question: What else will it look at?

18 "Answer: In-process specs, process execution,  
19 any potential deviations from the master batch record that  
20 could have occurred, the particulates associated with visual  
21 inspection, how that visual inspection effort went through,  
22 so there's a lot of aspects that need to be done before a  
23 product can be released and they have to all be reviewed by  
24 quality, quality assurance, and also a confirmational  
25 discussion will be had to assure that both Eagle and AMRI

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1 are in line to allow release of a batch.

2 "We're not limited -- it's not just release  
3 specs, it's one of many things.

4 "Question: Does AMRI -- will AMRI send its  
5 in-process analyses of the commercial batches to FDA for  
6 each batch?

7 "Answer: No.

8 "Question: Will FDA have access to the  
9 in-process data for these batches?

10 "Answer: If they request it, yes.

11 "Question: But only if they request it; right?

12 "Answer: Yes.

13 "Question: AMRI is not going to affirmatively  
14 send the in-process data to FDA; right?

15 "Answer: No.

16 "Question: But at the end of the process, if a  
17 commercial batch fails your in-process parameters but meets  
18 your release specs by the time it's released, the FDA would  
19 still let Eagle sell that commercial batch; right?

20 "Answer: I've already kind of discussed it  
21 doesn't matter. We would not release a batch if we didn't  
22 feel it conformed to the in-process specs.

23 "Question: I'm not asking --

24 "Answer: I can't speak for the FDA either.

25 "Question: I'm asking at the end of the process

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1 if a commercial batch fails your in-process parameters, but  
2 by the time it gets to the release it meets the release  
3 specs, the FDA would still let Eagle sell that product;  
4 right?

5 "Answer: I cannot answer for the FDA. I don't  
6 know.

7 "Question: Would the FDA look at your  
8 in-process data for each batch that is sold by Eagle?

9 "Answer: If they came in to the facility, they  
10 could.

11 "Question: Would they?

12 "Answer: I can't speak for the FDA.

13 "Question: Would AMRI expect for a batch that  
14 fails in-process parameters but meets the release spec and  
15 it is a batch that AMRI has released to Eagle to sell  
16 because it meets those release specs, AMRI would expect the  
17 FDA would allow Eagle to sell that product even though it  
18 failed the in process parameters; right?

19 "Answer: AMRI would not release the batch.

20 "Question: I didn't ask whether AMRI would  
21 release the batch. I'm asking for a batch that fails  
22 in-process parameters but makes it through the process to  
23 release it and it meets the release specs, and AMRI releases  
24 that batch to Eagle, AMRI would expect FDA to allow Eagle to  
25 sell that product because it meets the release specs;

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1 correct?

2 "Answer: Again, I repeat, AMRI would never  
3 release that batch.

4 "Question: You're not answering my question.  
5 I'm not asking you whether AMRI would release the batch.  
6 I'm telling you in a situation where AMRI releases a batch  
7 because it meets the release spec even though it has failed  
8 the in-process specs along the way, by the time it gets to  
9 release, it meets those release specs, AMRI releases it to  
10 Eagle, Eagle sells the product to a customer, FDA would  
11 allow Eagle to sell that batch to a customer because it  
12 meets the release specs; correct?

13 "Answer: Again, I can't answer that question.  
14 AMRI would not release the batch.

15 "Question: You understand you have to answer my  
16 questions today; right?

17 "Answer: I understand, but I can't answer the  
18 question because I can't see that as a hypothetical  
19 situation that can occur.

20 "Question: I'm asking you to assume it's  
21 occurring, okay?

22 "Answer: Okay.

23 "Question: Assume it's occurring. AMRI is  
24 making a batch. It has failed the in-process specs. By the  
25 time of release, it meets the release specs, so it failed

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1 the in-process specs but it meets the release specs. AMRI  
2 decides to release that batch to Eagle to sell. Eagle  
3 decides to sell that batch to a customer. FDA would allow  
4 that; right?

5 "Answer: If that is a hypothetical situation  
6 that occurred, although I don't believe it could occur,  
7 then, yes.

8 "Question: FDA wouldn't go in and say this  
9 batch failed the in-process specs, we're not going to allow  
10 Eagle to sell it; right?

11 "Answer: If they came in to the facility, yes,  
12 they very well could.

13 "Question: They could, but would AMRI expect  
14 that they would?

15 "Answer: If we did not follow our quality  
16 systems and what is put in place to control product going  
17 into the market, then, yes, I believe the FDA would come in  
18 and question that and want to know why we made that  
19 decision.

20 "Question: Let's assume that AMRI followed its  
21 in-process specs, let's say AMRI did an out-of-spec report,  
22 let's say AMRI followed every one of its in-process  
23 protocols to the letter of the protocol. It was out of  
24 spec. By the time of release, it was in spec.

25 "FDA comes in to AMRI, looks at all that data,



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1 looks at the release spec and sees that AMRI released a  
2 product that met the release specs even though it failed the  
3 in-process specs, FDA would still allow Eagle to sell that  
4 product to a customer? Right?

5 "Answer: Potentially, yeah. I don't know for  
6 sure. I can't answer for the FDA.

7 "Question: So AMRI made SVA007 through 009 in  
8 response to the CRL --

9 "Answer: Yes.

10 "Question -- correct?

11 "How were SVA007 to 009 made?

12 "Answer: According to the master batch record  
13 for each of those individual batches.

14 "Question: Were they made using the same  
15 process that was used for the registration batches?

16 "Answer: No, we made changes.

17 "Question: At a high level, what are the  
18 changes?

19 "Answer: High level, we increased or modified  
20 the way we calculated assay, sorry, the amount of  
21 vasopressin to ensure that our assay hit a new spec that we  
22 put in place, which I believe is 98 to 110 percent, as well  
23 as modified our pH adjustment steps and as well as the  
24 overall stabilization step that we added in.

25 "Question: AMRI is relying on data from batches

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1 007 to 009 to support Eagle's ANDA; right?

2 "Answer: Correct, yeah.

3 "Question: So the in-process parameter for pH  
4 for the process optimization and confirmation batches is  
5 3.42 to 3.50.

6 "Do you see that?

7 "Answer: Yes.

8 "Question: What would happen to a process  
9 optimization/confirmation batch if the pH is above 3.50?

10 "Answer: For the in process testing?

11 "Question: Yes.

12 "Answer: Then our quality team will identify  
13 that situation and have a discussion associated with Eagle's  
14 quality team to discuss the practicality whether that batch  
15 was viable for its intended use, which is to support the  
16 ANDA.

17 "Question: And then what would happen after  
18 that?

19 "Answer: It all depends on what their decision  
20 was on that.

21 "Question: Let's say that a pH of a process  
22 optimization slash confirmation batch was 3.54. You're  
23 saying that the quality team would have a discussion with  
24 Eagle's quality team to discuss whether the batch was viable  
25 for its intended use?

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1 "Answer: Yes.

2 "Question: And what would happen if Eagle's  
3 quality team and AMRI's quality team decided that that  
4 out-of-spec batch at 3.54 pH was still viable for its  
5 intended use?

6 "Answer: They then they would proceed to allow  
7 a continued effort to release the batch.

8 "Question: So a batch that fails this  
9 in-process spec of 3.42 to 3.50 would not simply be  
10 scrapped; right?

11 "Answer: No, I'm not saying that. It could  
12 still be scrapped, absolutely. Again, it's between the  
13 discussion of the two quality units and it's all about what  
14 the intended use of those batches is. In this case, they  
15 are for nonclinical, non-human uses. They are going for  
16 stability batches to support the ANDA and our current  
17 process optimization effort.

18 "Question: I'm sorry. To clarify, you changed  
19 the process or you've changed the in process controls?

20 "Answer: We changed the process.

21 "Question: How you very changed the process?

22 "Answer: By modifying how we adjust, when we  
23 adjust pH, the additional testing that is done with regards  
24 to the manufacturing batch record, who does the testing.  
25 We've also modified how we calculate the amount of API to

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1     add vasopressin to adjust on assay. We've added a  
2     stabilization step into the process, so there have been  
3     quite a bit of changes to the process since the time the  
4     registration batches were manufactured.

5             "Question: And if the pH of a batch ends up  
6     being 3.6 at the pre-filtration step, AMRI can still decide  
7     to release that batch for commercial sale; right?

8             "Answer: Not at the commercial stage, no.

9             "Question: AMRI can still decide to release  
10    that batch to Eagle for Eagle to sell commercially; correct?

11            "Answer: No, not for commercial.

12            "Question: Why not?

13            "Answer: Because the in-process spec for pH  
14    would not be met, which at that point for commercial as  
15    we've outlined here is 3.42 to 3.54 for pre-filtration.

16            "Question: Let's say at the step, the  
17    pre-filtration step, the pH is measured to be 3.60.

18            "Answer: Okay.

19            "Question: For a commercial batch.

20            "Answer: Mm-hmm.

21            "Question: So it fails the in-process spec.

22            "Answer: Yes.

23            "Question: However, it is within the release  
24    spec.

25            "Answer: Correct.

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1 "Question: AMRI could still release that batch  
2 to Eagle for commercial sale even though it failed the  
3 in-process control spec --

4 "Answer: No.

5 "Question: -- right?

6 "Answer: AMRI would not release it. They could  
7 not.

8 "Question: Why could they not?

9 "Answer: Our quality systems would not allow us  
10 to release a commercial batch with in-process steps that  
11 were not met.

12 "Question: Again, I'm asking if that commercial  
13 batch is 3.60 and it's within the release spec but it failed  
14 your in-process spec to that point, if AMRI decided to  
15 release it, the FDA would allow that; right?

16 "Answer: Again, AMRI would not release the  
17 batch, and I can't speak for the FDA on what they would  
18 allow.

19 "Question: I'm not asking you whether AMRI  
20 would release the batch or not. I'm telling you they do  
21 release the batch at 3.60 even though it failed their  
22 in-process spec. The FDA would not stop Eagle from selling  
23 that product; right?

24 "Answer: I don't know.

25 "Question: You've just been handed Exhibit 30,

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1 module 3.2.P.8.1, stability study -- stability summary and  
2 conclusions.

3 "Do you see that?

4 "Answer: Yes.

5 "Question: Let's turn back to Exhibit 30.

6 "Answer: All right.

7 "Question: Can you turn to the Bates number  
8 that ends in 47336?

9 "On the next paragraph it says, the slopes of  
10 the pH results for the three individual batches represented  
11 in Figure 1 were found statistically significant and  
12 slightly increasing over 24 months for the two to  
13 eight-degree Celsius storage condition.

14 "Do you see that?

15 "Answer: Mm-hmm.

16 "Question: Does AMRI agree that that is an  
17 accurate representation?

18 "Answer: Yes.

19 "Question: Later in the paragraph it talks  
20 about an out-of-spec sample.

21 "Do you see that?

22 "Answer: A single data point for batch SVA001?

23 "Question: Yes.

24 "Answer: Yes.

25 "Question: And it says hear the root cause of

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1 the OOS was determined to be batch SVA001 was released at  
2 the upper limit of the pH specification. The release value  
3 was 3.64 which rounds to 3.6.

4 "Do you see that?

5 "Answer: Yes.

6 "Question: Do you think it's accurate when  
7 Eagle says that the root cause of the OOS was that the batch  
8 SVA001 was released at the upper limit of the pH  
9 specification?

10 "Answer: I would agree with that, yes.

11 "Question: Okay. So this OOS report starting  
12 at the bottom of the second page has a root cause analysis.

13 "Do you see that?

14 "Answer: Yes.

15 "Question: And it looks like the authors of  
16 this report methodically went through a few different  
17 factors and ruled each one out one by one. Do you see that?

18 "Answer: Yes.

19 "Question: So the equipment was ruled out,  
20 personnel was ruled out, method was ruled out, materials was  
21 ruled out, data processing and calculations were ruled out  
22 as well.

23 "Do you see that?

24 "Answer: Yes.

25 "Question: On the final page in the top

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1 paragraph, authors of this report conclude that quote, 'the  
2 product is likely' -- quote, 'the product is the likely root  
3 cause of the high pH.'

4 "Do you see that?

5 "Answer: Yes.

6 "Question: Does AMRI believe that the product  
7 is likely the root cause of the high pH?

8 "Answer: Yes.

9 "Question: And if there were other root causes  
10 of the high pH, they would have been included in this  
11 report; right?

12 "Answer: As we don't have any other root causes  
13 identified that were able to be identified, this is the  
14 likely root cause, this product."

15 (End of videotaped deposition.)

16 THE COURT: All right. Mr. Moore?

17 MR. MOORE: Your Honor, just regarding the  
18 exhibits in the clip, pursuant to the designations, Eagle  
19 moves in PTX-73.

20 I understand there might be two exhibits you're  
21 going to move in.

22 MR. GOLDBERG: Yes. Par moves in PTX-135 and  
23 PTX-217.

24 MR. MOORE: No objection.

25 THE COURT: No objection? They're admitted.



1 (PTX-73, PTX-135 and PTX-217 were admitted into  
2 evidence.)

3 THE COURT: OOS is out of spec?

4 MR. GOLDBERG: Yes.

5 THE COURT: What's OOS?

6 MR. HALES: The actual manufacturer of --

7 THE COURT: Of the active ingredient?

8 MR. LASKY: Yes.

9 MR. BLACK: No, no. The company.

10 MR. LASKY: I'm sorry.

11 MR. BLACK: Company name. It's a cousin of  
12 AMRI.

13 THE COURT: Do you want to treat it as AMRI?

14 MR. HALES: I think that's fair.

15 MR. BLACK: That's our understanding.

16 THE COURT: And VASO1, is that the "original  
17 Vaso"?

18 MR. BLACK: Yes.

19 THE COURT: Okay. Thanks very much.

20 Next?

21 MR. BLACK: All right. Thank you, Your Honor.  
22 We're going to call Dr. Lee Kirsch. He's our peptide  
23 stability expert and I'm going to turn it over to Mr. Loeb  
24 to handle the examination.

25 THE COURT: All right. Thank you.

Kirsch - direct

1 MR. LOEB: Good afternoon. I'm Jonathan Loeb.

2 THE COURT: Good afternoon.

3 MR. LOEB: May we approach with some binders?

4 THE COURT: I'm sorry?

5 MR. LOEB: I said may we approach with some  
6 binders.

7 THE COURT: I think I've already got them. Oh,  
8 no I don't.

9 ... DR. LEE KIRSCH, having been duly  
10 sworn/affirmed as a witness, was examined and testified as  
11 follows...

12 DIRECT EXAMINATION

13 BY MR. LOEB:

14 Q. Good afternoon, Dr. Kirsch. I will let you sit down.

15 A. Good afternoon.

16 Q. Have you prepared slides to assist you with your  
17 testimony today?

18 A. I have, yes.

19 Q. And could you tell us a little bit about your  
20 professional background?

21 A. Sure. Let's take a look at the first slide.

22 Q. Here we go.

23 A. So I've had a long career in the area of  
24 pharmaceuticals, over 40 years, from 1994 to 2018. I was a  
25 professor at the University of Iowa in the college of

Kirsch - direct

1 pharmacy, in the division of pharmaceuticals.

2 Since 2019, I have been a professor emeritus at  
3 the University of Iowa, and prior to my academic career, I  
4 was a industrial scientist, senior research scientist and  
5 group leader at Eli Lilly and Company in their peptide and  
6 protein development division and I was there for 12 years  
7 before joining the faculty at the University of Iowa.

8 Q. You mentioned that your experience is in the field of  
9 pharmaceuticals. Could you explain what that is?

10 A. Certainly. So pharmaceuticals is the discipline that  
11 deals with pharmaceutical formulations and dosage forms and  
12 drug delivery systems, their design and properties and the  
13 relevant quality issues that are associated with  
14 formulations and products.

15 Q. And could you tell us a little bit about your  
16 education?

17 A. Sure. I received my Bachelor of Science in pharmacy  
18 and pharmaceutical science from Purdue University in 1975  
19 whereupon I was a community pharmacist for about three years  
20 and then went back to school and received my Ph.D. in  
21 pharmaceuticals at the Ohio State University.

22 Q. What has been the focus of your research?

23 A. So the next slide, please. My main area of research  
24 has been in the stability of drug and drug degradation,  
25 kinetics, especially in peptide drugs. Most of my

Kirsch - direct

1 publications deal with the stability of peptide drugs.

2 Q. And what exactly is a peptide drug?

3 A. So a peptide is a bio, a biopolymer or a biological  
4 polymer that's composed of amino acid residues and it's very  
5 similar to a protein, for example, although typically  
6 smaller than a protein.

7 Q. And you mentioned the term amino residue. What's  
8 that?

9 A. So amino acids are the building blocks of peptides and  
10 proteins. These are relatively small molecules that are  
11 linked together in a peptide by what's called a peptide  
12 bond. So they are the building blocks of the peptides and  
13 proteins.

14 Q. Why is the stability of peptide drugs relevant to this  
15 case?

16 A. Well, because vasopressin is a peptide hormone and the  
17 issues in these particular patents have to deal with  
18 stability.

19 MR. LOEB: Your Honor, we offer Dr. Kirsch as an  
20 expert in pharmaceuticals. In particular, peptide  
21 pharmaceutical formulation and peptide stability.

22 MR. HALES: No objection.

23 THE COURT: All right. Thank you.

24 MR. LOEB: Okay.

25 BY MR. LOEB:

Kirsch - direct

1 Q. Now, you mentioned that this case is about  
2 vasopressin. We've already heard about that. Do the  
3 patents-in-suit describe the molecular structure of  
4 vasopressin?

5 A. They do. Let's take a look at the next slide.

6 So this is an excerpt from the '209 patent,  
7 JTX-2, in which the molecular structure of vasopressin is  
8 displayed, and so the individual atoms and the individual  
9 amino acids which are, which come together to form  
10 vasopressin are laid out in this particular figure and the  
11 individual amino acids you'll notice are identified by their  
12 three letter abbreviation.

13 For example, if you look on the lower left-hand  
14 corner, you see gly, which stands for glycine. Next to that  
15 is arg, which is arginine. These are amino acids which are  
16 linked together by peptide bonds.

17 Vasopressin is a cyclic peptide, so there's  
18 actually a ring structure made up of six amino acid residues  
19 which are joined together by what's called a disulfide bond.  
20 If you look in the middle of the picture, you see two S's  
21 that are joined together. That's what's called a disulfide  
22 bond.

23 Q. Now, do peptide drugs like vasopressin present any  
24 special challenges for formulators when making stable  
25 pharmaceutical formulations?

Kirsch - direct

1 A. Yes. Peptides and proteins as well are particularly  
2 susceptible to various types of instability processes, both  
3 in terms of physical instability and also in terms of  
4 chemical instability. This arises because they typically  
5 contain multiple sites where degradation can occur and  
6 degradation would typically occur at these sites  
7 simultaneously, which makes the understanding of their  
8 instability rather complicated.

9 Q. Do the patents-in-suit explain anything about what  
10 vasopressin does?

11 A. Yes, they do. Let's go to the next slide.

12 The patent explains early on in the detailed  
13 description of what vasopressin is. Again, it's a peptide  
14 hormone. It regulates water retention in the body. It can  
15 also act as a neurotransmitter that controls various bodily  
16 functions and it can cause a rapid increase in blood  
17 pressure, which is, of course, as we've heard, the  
18 therapeutically useful part of vasopressin's action in  
19 counteracting severe hypotension, for example, that's seen  
20 in septic shock.

21 Q. This portion of the patent that you've reproduced  
22 here, that's the '209 patent at column 38 through 51?

23 A. Yes, that's correct.

24 Q. Now, do the patents-in-suit address any particular  
25 problem concerning vasopressin?

Kirsch - direct

1 A. Yes, they do. Look at the next slide.

2 So the patents are directed to improved  
3 formulations over the prior art and with improvements,  
4 particularly in stability.

5 Q. Okay. And this is from the '209 patent, JTX-2 at  
6 column 53, lines 56 through 59?

7 A. Correct.

8 Q. And how is it that the patents-in-suit provide  
9 advantages in stability?

10 A. So, the main advantage that -- the main way in which  
11 they provide an advantage is through pH control. Let's go  
12 to the next slide.

13 In particular, the inventors have identified the  
14 pH of optimal stability as being within the pH range 3.7 to  
15 3.9. The patent also has some specific impurity limits in  
16 it.

17 Q. Now, what particular legal questions have you been  
18 asked to address in this case?

19 A. I've been asked to address infringement and issues  
20 associated with validity.

21 Q. Okay. Now, Dr. Coralic already identified the '209  
22 patent, but can you turn to JTX-3 in your binder and tell me  
23 what that is?

24 A. So this is the so-called '785 patent, vasopressin  
25 formulations in use in the treatment of hypotension.

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1 Q. And that's U.S. Patent 9,750,785?

2 A. That's correct.

3 Q. Okay. And have you reviewed these patents?

4 A. I have.

5 Q. Okay. And are there any significant differences  
6 between the specification of the '785 and the '209 patent?

7 A. No, there isn't.

8 Q. All right.

9 THE COURT: Just to be clear, you mean written  
10 description, right, for the specification? The claim is  
11 different, pretty substantial.

12 MR. LOEB: That's correct, Your Honor. That's  
13 what I intended to ask. Maybe we can confirm that with Dr.  
14 Kirsch.

15 BY MR. LOEB:

16 Q. What I meant to ask was the, part of the patent  
17 specification that comes before the claim?

18 A. Yes, that's correct. They're the same.

19 Q. All right. Now, you mentioned that there's a  
20 particular pH range which is identified in the patent.  
21 Before we get to that, could you explain what pH is?

22 A. Sure. Let's take a look at the next slide.

23 So pH is a measure of the concentration of  
24 hydronium ions. Hydronium ions are protonated water  
25 molecules which give rise to the acidity of an aqueous



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1 solution. So the higher the concentration of hydronium ion,  
2 the greater the acidity is in that solution. And acidity  
3 turns out to be a very important property of the solution,  
4 which can control various characteristics of those things  
5 that are dissolved in the solution and solute is what we  
6 call it. For example, there's stability. Also, solubility,  
7 their ionic state and such things as that.

8 Q. Just to narrow that down a little bit, can the pH have  
9 an effect on the stability of drug molecules?

10 A. Absolutely.

11 Q. All right. Now, how are pH units expressed  
12 mathematically by a scientist?

13 A. So let's go to the next slide.

14 pH is a logarithmic scale. So what I've shown  
15 here is the -- a pH range of one unit, the pH between three  
16 and four, and correlated to the acid concentration that  
17 corresponds to those pH values.

18 So you can see that a pH three, the acid  
19 concentration is one millimolar, and then if you look at pH  
20 four, which is one unit away, as I mentioned, there's a  
21 tenfold decrease then. The acid concentration is tenfold  
22 less than at pH three.

23 Even small differences between pH value, let's  
24 say a difference of two-tenths of a unit can be a  
25 substantial difference in the concentration of acid in that

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1 solution. So, for example, in going from a pH of 3.8 to a  
2 pH of 3.6, we would see almost a 60 percent increase in acid  
3 concentration. And even for a tenth of a pH unit, going,  
4 say, from pH 3.7 to 3.6, the concentration of acid would  
5 increase by over 25 percent.

6 Q. Can you explain the importance of pH to the  
7 stability -- excuse me. That was my last question. Can you  
8 explain the importance of stability to pharmaceutical  
9 products?

10 A. Sure. Let's look at the next slide, which attempts to  
11 capture the -- basically, the life cycle of a drug substance  
12 used in a pharmaceutical product and we have seen this  
13 picture before.

14 The API, which is the active pharmaceutical  
15 ingredient, has to be synthesized. Then it's stored and  
16 then it's incorporated into what we call, into a  
17 pharmaceutical product. It's formulated and goes through  
18 what we call a finish manufacturing operation, which are  
19 then shipped, stored, and ultimately administered.

20 And throughout that, throughout that life cycle,  
21 if you will, a drug molecule is going to be stressed in  
22 various ways by the environment or the conditions in which  
23 it finds itself and those -- that stress can cause chemical  
24 changes, and those chemical changes are what we call  
25 chemical instability pathways, so typically, drugs undergo

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1 hydrolysis or oxidation, isomerization, polymerization or  
2 photo chemical decomposition. And what happens is as they  
3 degrade, the drug potency is lost as the drug degrades. The  
4 levels of impurity will increase as well. And so this can  
5 have an impact on the safety and efficacy of the drug  
6 product.

7 Q. Now, how is drug stability assessed?

8 A. So typically, one conducts drug stability tests.  
9 Let's go to the next slide.

10 So what one would do would be to take a batch of  
11 a drug and composed of the individual units and one would  
12 subject that batch to a predetermined protocol, which  
13 defines the conditions of its storage and treatment and then  
14 using a predetermined sampling schedule, will remove samples  
15 from the -- from the batch periodically. Take those samples  
16 and test them by various analytical methods, which are  
17 intended to relate to the critical quality attributes of  
18 the, of the drug product, one such thing, for example, is  
19 potency or impurity, clarity, pH, et cetera.

20 One then takes those measurements and compares  
21 them to the specifications to that drug product to see  
22 whether or not the drug product complies with the  
23 specifications and therefore has the appropriate quality  
24 that the drug product is intended to have.

25 Q. And how are specifications for drug products

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1 determined?

2 A. Well, typically, the developer of the drug product  
3 will identify reasonable specifications or what they think  
4 the product can -- can -- can stay within, and then propose  
5 those specifications to the FDA. The FDA reviews them and  
6 would approve them.

7 Q. All right. Now, I'd like to talk a little bit more  
8 about the structure of the vasopressin molecule.

9 Do the patents describe the arrangement of amino  
10 acids in vasopressin?

11 A. Sure. Let's look at the next slide.

12 So, again, let's start at the upper left-hand  
13 site of this slide. This is the same picture that we saw  
14 before. This is the chemical structure of vasopressin as it  
15 appears in the patent.

16 There are a variety of ways in which this  
17 structure can be depicted. If we go to the right, then this  
18 is a balloon-like structure. It shows the individual amino  
19 acids and the little ovals there that are connected to one  
20 another typically by peptide bonds, and then there's a  
21 cyclic structure, as I mentioned before, that is closed by a  
22 disulfide bond.

23 So this is one way in which we can represent the  
24 cyclic nature of that -- of that peptide. One could just  
25 stretch that, that diagram out and get the figure that's

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1 below it, which is the linear arrangement or linear sequence  
2 of amino acid residues, starting with what's called  
3 cysteine, identified here by the three letter code, Cys, and  
4 then next to it is a tyrosine and phenylalanine and so forth  
5 until the other end of the molecule has a modified glycine  
6 amino acid.

7 So that's a linear sequence. And below that  
8 linear sequence is the same sequence as identified in the  
9 patent by the single letter abbreviation for amino acid  
10 residue, so now C stands for Cysteine, Y stands for  
11 tyrosine, F for phenylalanine, and so forth.

12 And then this is what's identified in the  
13 patent, in Table 1 of the patent of the '209 patent as  
14 vasopressin and SEQ ID Number 1.

15 Q. Now, the chemical structure that you show here, that  
16 was from columns 3 and 4 of the '209 patent?

17 A. Correct.

18 Q. Is that right?

19 A. That's correct.

20 Q. Okay. What did the patent teach about the particular  
21 impurities that are found in vasopressin?

22 A. So let's go to the next slide. And this is another --  
23 additional information taken from the patent.

24 So in Table 1 of the '209 patent, they list a  
25 list of vasopressin-related substances and they identify

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1       them by name, and then a second column, they identified them  
2       by their sequence, and then they've assigned to those  
3       impurities a sequence identification number.

4               And then in Table 3 of that same patent they  
5       have -- they have selected out a group of five of those  
6       impurities. These are actual degradation products of  
7       vasopressin, and, again, they've identified them by name,  
8       and in this case, by their -- their molecular formula and  
9       also their molecular mass.

10              So these are the -- these actually are the  
11       degradation products which are -- which are contained in the  
12       dependent claims of the patent.

13       Q.       Okay. Now, are you aware of anyone that identified  
14       the particular impurities that are found in vasopressin at a  
15       time before the patents?

16       A.       No. I could find nothing in the prior art which  
17       identified specific impurities.

18       Q.       All right. I'd like to just focus on those particular  
19       impurities that are in the claims for a moment.

20              Is it possible to illustrate the changes on the  
21       chemical structure of vasopressin?

22       A.       Yes. Let's take a look at the next slide.

23              So in this slide again I've reproduced the  
24       chemical structure as it appears in the patent, but also  
25       included various, at various points in this molecular

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1 structure where bonds are broken or modified to give rise to  
2 the degradation product.

3 So, for example, on the left-hand side, lower  
4 left-hand side, gly9 is formed by breaking the bond between  
5 a carbon and a nitrogen and actually then that ammonia, that  
6 nitrogen H<sub>2</sub>N is replaced by an OH group, so that gives rise  
7 to gly9.

8 Then ASP 5 we see in the lower middle, again,  
9 breaking of a carbon nitrogen bond and then the formation of  
10 a, of a different amino acid called aspartic acid.

11 And then we also see glu4, which is another one  
12 of these carbon nitrogen bond breakages and the placement of  
13 an OH group which forms -- then E, asparagine is a  
14 rearrangement of the asparagine residue. And the acetyl  
15 group can attack the amino terminus of the peptides, the  
16 cysteine, and form an atom.

17 Q. And how in practice did scientists identify and  
18 quantitate the impurities within a peptide drug like  
19 vasopressin?

20 A. Well, there are a variety of methods, analytical  
21 methods that they can use. Let's go to the next slide.

22 This gives an example from the patent. Figure 6  
23 of a chromatographics separation of the impurities in the  
24 sample of vasopressin where the individual impurities have a  
25 characteristic, what's called the retention time, so they

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1 have a characteristic peak and the identity of the degradant  
2 can be identified by their retention time, peak position,  
3 and they can be quantified in terms of their composition by  
4 the peak area or the peak height.

5 Q. Okay. Now I'm turning to the patent claims. Which  
6 patent claims are asserted against Amneal and Eagle in this  
7 case?

8 A. So let's go to the next slide.

9 The patent claims, the '209 patent claims that  
10 are asserted against Eagle are 1, 4, 5 and 7. The patent  
11 claims asserted against Amneal are 1, 2, 4, 5, 6, 7, 8. And  
12 for the '785 patent, the patent claims asserted against both  
13 Eagle and Amneal are 1, 5 and 8.

14 Q. And have you analyzed whether Eagle will infringe the  
15 asserted claims if it has a commercial product approved by  
16 FDA?

17 A. Yes.

18 Q. Okay. And what standard were you instructed to apply  
19 to address whether Eagle infringes Par's patent claims?

20 A. So let's go to the next slide. I was instructed this  
21 two-step analysis for the claims are construed by the Court  
22 and then the claims are applied in a claim-by-claim and  
23 limitation-by-limitation basis to Eagle's product and that  
24 Eagle's product must satisfy every limitation or requirement  
25 of the claim.



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1 Q. What is your understanding of the standard for  
2 inducing infringement?

3 A. So let's go to the next slide. Inducing infringement,  
4 Eagle is liable for indirect infringement if it induces  
5 direct infringement of a patent by another. In the context  
6 of the cases involving pharmaceutical products, liability  
7 for inducement may be established if the package insert for  
8 the product instructs medical professionals to either  
9 perform the patented method or use a claim composition.

10 Q. And did the Court construe any of the limitations  
11 which are relevant to your analysis?

12 A. Yes. Let's go to the next slide.

13 So the Court looked at the term administering to  
14 the human a unit dosage form and construed it to have its  
15 plain and ordinary meaning. Vasopressin was construed to  
16 mean arginine vasopressin as described in SEQ identity  
17 number one.

18 And the unit dosage form has a pH of 3.7 to 3.9,  
19 was given its ordinary meaning.

20 Q. Did you apply the Court's constructions in your  
21 analysis?

22 A. I did.

23 Q. And what meaning did you give to terms that were not  
24 construed by the Court?

25 A. The plain and ordinary meaning.

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1 Q. Okay. Now, in this case, we're going to see pH values  
2 that are expressed to the second decimal place. For  
3 example, pH 3.65.

4 Would a POSA interpret such a measurement as  
5 within or without the unit dosage form as a pH of 3.7 to  
6 3.9?

7 A. Well, a value of 3.65, a person of ordinary skill  
8 would round to the tenth decimal point and would give it a  
9 value of 3.7, so that would fall within the claimed range.

10 Q. All right. And why would a person of ordinary skill  
11 use that rounding procedure?

12 A. Well, this is standard practice in the art. It's also  
13 a practice which has been described in detail by the United  
14 States Pharmacopeia, which is the standard reference that  
15 people in the field use to guide them in, in analytical  
16 methods in other aspects of pharmaceuticals.

17 Q. So what would the meaning of 3.7 to 3.9 be to an  
18 ordinarily skilled artisan if expressed to the hundredth  
19 point?

20 A. It would be 3.65 to 3.94.

21 Q. Now, do you have an opinion as to the level of skill  
22 of a person of ordinary skill in the art as to the  
23 patents-in-suit?

24 A. Yes, I do. Let's look at the next slide.

25 So in my view, a person of ordinary skill in the

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1 art would have a master's, PharmD or Ph.D. in the field of  
2 pharmaceutical sciences or a related discipline and several  
3 years of experience in the development of pharmaceutical  
4 dosage forms.

5 A person of ordinary skill in the art may also  
6 have less formal education and a greater amount of  
7 experience.

8 A person of ordinary skill would have had access  
9 to and would have working collaboration with persons having  
10 several years of experience in the formulation of drug  
11 products as well as other professions in the drug  
12 development field, such as pharmacologists, chemists,  
13 biologists, or clinicians.

14 Q. Now, have you compared your definition -- well, first  
15 of all, I'd like to use the acronym POSA for a person of  
16 ordinary skill in the art. Is that okay?

17 A. Sure.

18 Q. Have you compared your definition of a POSA to the  
19 definitions provided by defendants' experts Dr. Park and Dr.  
20 Winter?

21 A. Yes, I have.

22 Q. And would it affect your opinions if you applied the  
23 POSA definition provided by defendants' experts as opposed  
24 to your own?

25 A. No, it would not.

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1 Q. What is your opinion as to what a POSA would consider  
2 the relevant time period to assess pH of the claimed  
3 vasopressin pharmaceutical compositions?

4 A. So let's go to the next slide. A person of ordinary  
5 skill would understand that the pH could be measured at any  
6 time during the formulation, formulation shelf life.

7 Q. And why is that?

8 A. Well, the plain language of the claim, for example,  
9 the '209 claim says administering to a human a unit dosage  
10 form wherein the unit dosage form has a pH of 3.7 to 3.9.  
11 So administering to the human is done within the period of  
12 the shelf life of the product, so that would -- so any time  
13 during the shelf life, the pH could be compared to the  
14 claimed range.

15 Q. And what about the claim language of '785, claim 1?

16 A. It's very similar. It says, where in the unit dosage  
17 form has a pH of 3.7 to 3.9.

18 Q. And what's your conclusion as to how that would be  
19 interpreted?

20 A. I think that would be interpreted in exactly the same  
21 way, that a pH would be within that range at any time during  
22 the shelf life.

23 Q. All right. Have you analyzed whether the written  
24 description of the patent or the file histories of the  
25 patents redefine the meaning of the pH limitations to mean

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1 something other than what you've just explained?

2 A. Yes. I didn't see anything that changed the  
3 definition.

4 Q. Okay. And at the very beginning of the presentation,  
5 you mentioned that the asserted claims also contain impurity  
6 limitations as well.

7 When do the impurity limitations need to be met  
8 by accused products in order to show infringement?

9 A. So the next slide, please. So the impurity  
10 limitations, the pH limitations must be satisfied at the  
11 same time, so during the shelf life of the product.

12 Q. And why is that?

13 A. Because of the plain language of the claims. Claim 1  
14 of the '209 patent says administering to the human a unit  
15 dosage form, wherein the unit dosage form has a pH of 3.7 to  
16 3.9; the unit dosage form further comprises impurities that  
17 are present in an amount of 0.9 to 1.7 percent.

18 Q. And how would a POSA interpret the way that is  
19 phrased?

20 A. That the impurity limitations and the pH limitations  
21 need to be met at the same time.

22 Q. And what about '785, claim 1?

23 A. Well, it's very similarly written in '785. It says  
24 the unit dosage form further comprises impurities that are  
25 present in amount of 0.9 to 1.7 percent and where in the

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1 unit dosage form has a pH of 3.7 to 3.9.

2 Q. Did you analyze Eagle's documentation of its proposed  
3 ANDA product and form an opinion as to whether that product  
4 would be likely to satisfy the limitations of the asserted  
5 claims?

6 A. Yes, I did.

7 Q. Okay.

8 THE COURT: So can I just ask? You said, you  
9 used this word documentation of its proposed ANDA product,  
10 and I have heard, like, for instance, at the pretrial  
11 conference Mr. Black referred to the ANDA. Is there a  
12 distinction?

13 MR. LOEB: Well, I don't want to testify, but --

14 THE COURT: Well, you asked the question. He  
15 answered it.

16 MR. LOEB: Okay.

17 THE COURT: So he must have known what you  
18 meant.

19 MR. LOEB: Okay.

20 THE COURT: I want to make sure.

21 MR. LOEB: An ANDA is a living document.  
22 There's an initial application which then, depending on, you  
23 know, additional data that the applicant generates or  
24 communications with FDA, there's supplements and amendments  
25 and so forth that can occur over time until such time as the

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1       ANDA is either approved or --

2               THE COURT:   You just said the ANDA.   So does the  
3       ANDA get modified?   In other words, I think we probably are  
4       on the same page.   I interpreted, especially going back to  
5       the pretrial where Mr. Black was saying can we get some  
6       agreement to authenticate, that maybe the ANDA was kind of  
7       like you file the initial application and then everything  
8       that follows until there's either approval or we're done  
9       with the ANDA.

10              MR. LOEB:   Right.   I mean, I think that's the  
11       way that I used the term.

12              THE COURT:   And that would be the same thing as  
13       the documentation, the term you used?

14              MR. LOEB:   Yes, Your Honor.

15              THE COURT:   All right.   What do you think?

16              MR. BLACK:   I've been fairly accused of  
17       imprecision.   ANDA is an ANDA number.   That's an application  
18       that's filed into many, many modules, 3.2, dozens of  
19       modules.   As additional edits are made to the ANDA,  
20       additional data comes in, that information is input into the  
21       FDA database and the ANDA all under a single ANDA number  
22       gets amended effectively.

23              THE COURT:   Right.   So it's all effective.   So  
24       when I speak of ANDA, at this point it's everything that has  
25       been filed from the section, the original filing to what's

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1 in the FDA file?

2 MR. BLACK: Correct.

3 THE COURT: That's what you think. Mr. Hales,  
4 do you disagree?

5 MR. HALES: And I think that is what is the  
6 suggestion of the ANDA is.

7 THE COURT: Perfect.

8 MR. HALES: I don't know if the suggestion is  
9 all of that is admitted or not.

10 MR. BLACK: It's certainly not admitted.

11 MR. HALES: Correct.

12 THE COURT: I want to make sure I'm not missing  
13 something. So is CRL, is that part of the ANDA?

14 MR. HALES: Yes.

15 MR. BLACK: Yes.

16 THE COURT: Your response to the CRL is part of  
17 the ANDA?

18 MR. HALES: Yes.

19 THE COURT: We can all refer to it as part of  
20 the ANDA.

21 MR. BLACK: Yes.

22 THE COURT: Thank you.

23 BY MR. LOEB:

24 Q. So we're on the same page, Dr. Kirsch, is that your  
25 understanding of the way people in the field use the term



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1       **ANDA?**

2       A.       Yes, that's correct.

3       Q.       All right. So did you review the portions of the ANDA  
4       which describe how Eagle is going to manufacture and test  
5       its product?

6       A.       Yes. Yes, I did.

7       Q.       How does Eagle measure the pH in vials of its  
8       products?

9       A.       So let's go to the next slide.

10               So the procedure that they use, they have a  
11       batch of 25,000 vials, which is about their commercial batch  
12       size, and then they would select, randomly select five vials  
13       from that -- from that batch.

14               Now, the pH in each individual vial may be  
15       different. I mean, there are differences between the pH and  
16       the individual vials. They take five of them and they pour  
17       the contents together and then measure the pH within the --  
18       where the combined content of five vials.

19               So to the extent that the pH is different in  
20       each of those vials that they selected, then basically, they  
21       are -- what they measure is the combined pH of those five  
22       vials.

23       Q.       So what effect does that have on the pH or the  
24       measurement as compared to the pH in the individual vials  
25       that Eagle produces?

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1 A. Well, basically, it masks the -- the differences that  
2 one sees, because they're combining contents together.

3 Q. Now, if we could come back to the claims that are  
4 asserted against Eagle, have you formed an opinion as to  
5 whether or not Eagle would be authorized to sell products  
6 that are more likely than not to infringe claims 1, 4, 5 and  
7 7 of the '209 patent and likely, and also more likely than  
8 not infringe claims 1, 5 and 8 of the '785 patent?

9 A. Yes, I have formed an opinion. I believe that they  
10 will infringe the patent.

11 Q. Now, does Eagle contest the infringement of every  
12 element of the asserted claims?

13 A. No, they don't.

14 Q. All right. Let's start with your analysis of the  
15 '785 patent. What are the requirements of '785 patent,  
16 claim 1?

17 A. So let's go to the next slide.

18 So claim 1 has four elements that relate to the  
19 pharmaceutical composition comprising a unit dosage form,  
20 the concentration of vasopressin that's present in the  
21 dosage form, and impurities that are present, and those  
22 three elements have been stipulated to, so the element of  
23 claim 1 that is under consideration now is the pH claim of  
24 3.7 to 3.9.

25 Q. Okay. So for that reason I'd like to focus your

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1 attention on the pH limitation, and if we could please look  
2 in your binder at PTX-1427.

3 Would you tell me what 1427 is?

4 A. So 1427 is one section of Eagle's ANDA which describes  
5 the specification for their vasopressin product.

6 Q. Okay. And if we -- have you prepared a slide that  
7 illustrates specifically the pH specification?

8 A. Yes. Let's take a look at the next slide.

9 Q. So what is the release specification for Eagle's ANDA  
10 product?

11 A. So the release specification is listed as 3.4 to 3.6.

12 Q. And when does Eagle measure the release pH of its ANDA  
13 product?

14 A. So once the filling operation is complete, then  
15 they -- we have all 25,000 vials, they would select five of  
16 those vials and make a measurement of pH.

17 Q. And what is the significance of a release  
18 specification?

19 A. Well, this controls whether or not one can release or  
20 put the batch into the market for sale.

21 Q. And what is the stability specification, which is the  
22 next column over to the right in Table 1 of PTX-1427 that  
23 we're looking at?

24 A. So the stability specification is the same as the  
25 release specification, 3.4 to 3.6.

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1 Q. Now, when does Eagle test its product against the  
2 stability specification?

3 A. Well, Eagle selects batches to put on stability and  
4 then they measure pH throughout the shelf life of the  
5 product and the conditions that they are interested in. So  
6 I think Eagle has committed to putting the first three  
7 commercial batches on stability and then to put one batch on  
8 stability every year after that.

9 Q. So will Eagle test the stability of every batch of its  
10 product that it's going to sell?

11 A. No, they won't.

12 Q. And within any given batch, let's assume that it is  
13 being subjected to a stability study. What percentage of  
14 vials will Eagle actually test in the stability study?

15 A. Well, clearly, if you have 25,000 vials, then you're  
16 testing five vials, you know, maybe nine times or so. Not a  
17 great percentage of the vials are actually being tested.

18 Q. Okay. Could you please look in your binder for  
19 PTX-208. Can you tell me what that is, please?

20 A. So 208 is again an excerpt from Eagle's ANDA, which  
21 compiles -- in which they've compiled the stability data for  
22 their registration batch SVA1.

23 Q. Okay. And what is a registration batch?

24 A. So a registration batch is the batches that Eagle  
25 prepared or that a manufacturer prepared to demonstrate that

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1       their product has the appropriate quality characteristics  
2       that they have set forth by the specification.

3       Q.       And I meant to ask a question about this document,  
4       PTX-1427, before we talk more about 208.

5               Why is it your opinion that Eagle is seeking  
6       authority to sell products that if used as intended are  
7       likely to have a pH between 3.7 and 3.9 at some point during  
8       the proposed shelf life given the fact that their release  
9       and stability specifications are 3.4 to 3.6.

10       A.       Because we have seen data which demonstrates that if a  
11       release batch at the upper end of their release  
12       specification, that that batch will in all likelihood have  
13       pH values within the claimed range.

14       Q.       Okay. Now I'd like to turn the attention back to  
15       PTX-208, the stability data.

16               Have you prepared a slide which illustrates the  
17       relevant part of PTX-208?

18       A.       Yes. Let's look at that slide.

19               So this is an excerpt from that PTX-208, which  
20       contains the pH data, so it shows the pH measurements over  
21       the course of 24 months.

22       Q.       Okay. And I think you mentioned that this is for  
23       batch SVA001. What condition for this batch is this table  
24       illustrating?

25       A.       This is the refrigerated condition.

Kirsch - direct

1 Q. Okay. This is at the Bates number ending in 276?

2 A. Correct.

3 Q. All right. Now, what did you see when you looked at  
4 the pH for this batch?

5 A. So the pH went as high as 3.7, 3.8 and 3.7 at the  
6 24-month time point. So at the very last column there  
7 highlighted, you can see the pH within the claimed range.

8 Q. All right. Now, what's the pH that was measured in  
9 the stability study for this batch at 18 months?

10 A. So 18 months, the value that's reported is 3.6.

11 Q. And what can you determine about when the pH of this  
12 batch increased from pH 3.6 to 3.7 and 3.8?

13 MR. HALES: Your Honor, I would object. This  
14 calls for speculation.

15 THE COURT: There's a way to answer it without  
16 speculation, so I'm going to let the question go. It could  
17 be speculation. Let's see what the answer is.

18 BY MR. LOEB:

19 Q. I'm sorry. Go ahead.

20 A. No. I would say, you know, based on the measurements  
21 that are made, and, of course, not all of the vials are  
22 tested, the data indicates that pH changed somewhere between  
23 18 and 24 months.

24 Q. Now, so this is registration batch SVA001. How many  
25 registration batches did Eagle make?

Kirsch - direct

1 A. Three.

2 Q. And did Eagle --

3 THE COURT: Hold up, hold up. Sorry. Give me a  
4 second.

5 THE WITNESS: Sure.

6 THE COURT: Okay. Thank you.

7 BY MR. LOEB:

8 Q. Did Eagle ever present these data for batch SVA001 to  
9 the FDA?

10 A. Yes, they did.

11 Q. And has Eagle ever informed FDA that SVA001 is no  
12 longer represent representative of its proposed ANDA  
13 product?

14 A. No. In their most recent submission, it's labeled as  
15 a representative batch.

16 Q. And assuming that FDA approves Eagle's product, will  
17 Eagle be able to sell commercial product with the same  
18 characteristics as SVA001?

19 A. Yes.

20 Q. Has Eagle ever changed the release specification for  
21 its ANDA product?

22 A. No.

23 Q. And if you look at the values that you pointed us to  
24 in the 24-month column, how do those values compare to  
25 Eagle's stability specification for its product?

Kirsch - direct

1 A. So those values are outside the stability  
2 specification.

3 Q. And if you squint in that same table, it says  
4 PR661354. What is that?

5 THE COURT: Could you just stop for one second?

6 MR. LOEB: Yes, Your Honor.

7 THE COURT: You can repeat it. Okay. Sorry.

8 Thank you very much.

9 BY MR. LOEB:

10 Q. All right. What is PR661354?

11 A. So this refers to a report and out-of-specification  
12 investigation and report that was conducted on this --  
13 because of this out-of, out-of-specification result.

14 Q. Okay. Could you look in your binder for PTX-53?  
15 Could you tell me what that is?

16 A. So that is PR661354, the out-of-specification report  
17 that was conducted to investigate those pH values.

18 Q. Have you prepared a slide that blows up the relevant  
19 part of the document?

20 A. Sure. Let's take a look at the next slide.

21 So this is the -- this is from the title page of the  
22 report, and then from the discussion of the results in which  
23 the investigator stated that there was no assignable root  
24 cause was found that could be attributed to laboratory or  
25 testing sources of error.



Kirsch - direct

1           So what they do in these investigations, they  
2           look to see whether or not there's some assignable root  
3           cause. For example, because of an analytical error or some  
4           other error that had occurred in collecting that data. And  
5           what they conclude in this report is that there was no  
6           assignable -- no assignable root cause was found that could  
7           be attributed to analytical or laboratory testing sources of  
8           error. And they go on to say that the product is the likely  
9           root cause of the high pH.

10          Q.       So in your view, what is the significance of this  
11          passage, which is at the Bates number ending in 548 in  
12          PTX-53?

13          A.       Well, what they are concluding there is that it is the  
14          product itself that gave rise to the out of --  
15          out-of-specification pH value.

16          Q.       Can you please look at PTX-1435 in your binder.

17          A.       Okay.

18          Q.       And what's that?

19          A.       So this is the latest, or this is, again, an excerpt  
20          from the Eagle ANDA. This is the latest stability summary  
21          and conclusion section of their ANDA where they discuss  
22          their stability results.

23          Q.       And when was this particular version of the stability  
24          summary and conclusion submitted to FDA by Eagle?

25          A.       So this occurred in June of this year, 2021.

Kirsch - direct

1 Q. All right. Does the stability summary and conclusion  
2 module, which is PTX-1435, describe the pH results for  
3 SVA001?

4 A. Yes, they do. Let's go to the next slide. Excerpts  
5 from this, from this -- from the discussion of the stability  
6 data for the registration batches and there's a number of  
7 salient points that can be observed in this discussion.

8 Q. Okay. So, first, does this document provide the  
9 release pH for SVA001?

10 A. Yes, it does. It says in the second highlighted  
11 section that the pH value at release was 3.64.

12 Q. Okay. And does this stability summary and conclusion  
13 that Eagle recently provided to FDA explain how Eagle  
14 handles pH values which are out to the hundreds?

15 A. Yes. In the first highlighted section, this is  
16 discussed, and it says that the -- the pH results of 3.35  
17 and 3.64 represent the lower and upper bounds of the pH  
18 specification 3.4 to 3.6. They describe in the sentence  
19 before that it's based on -- well, that it's based on  
20 rounding.

21 Q. Okay. And does this passage inform you how a POSA  
22 would understand the claimed pH range of 3.7 to 3.9?

23 A. Yes. It means -- it is consistent with what I've said  
24 before, that the claimed pH range is 3.65 to 3.94 based on  
25 rounding.

Kirsch - direct

1 Q. Now, was SVA001 within the release pH specification  
2 when it was released?

3 A. Yes. They indicate that it was released at 3.64,  
4 which rounds to 3.6, so that was within the release  
5 specification. SVA001.

6 Q. What did Eagle tell the FDA about the 3.7 and 3.8 pH  
7 results?

8 A. Well, in the second highlighted section, it says, root  
9 cause of the out-of-specification result was determined to  
10 be the batch. SVA001 was released at the upper limit of the  
11 pH specification. The release value was 3.64, which rounds  
12 to 3.6.

13 Q. Is Eagle's statement here from June of 2021 consistent  
14 with your infringement opinion?

15 A. Yes.

16 Q. Now, is it your opinion that every batch of Eagle's  
17 product will meet the claimed pH range?

18 A. No. It's my opinion that those batches that are  
19 released at the upper range of their release specification  
20 are likely to infringe.

21 Q. Assuming that FDA approved Eagle's ANDA as it stands  
22 currently, could Eagle release a commercial batch with a pH  
23 of 3.64?

24 MR. HALES: Objection, Your Honor. I don't  
25 think it's appropriate for him to comment on what the FDA

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1 would or wouldn't approve. As you know, there's another  
2 part of the specification that he's not talking about.

3 THE COURT: Well, I thought there might be a  
4 more fundamental objection that I've got questions about.  
5 Don't we need an FDA expert to testify about that or is it,  
6 more important, is it not just a legal question?

7 MR. LOEB: I'm asking Dr. Kirsch, in his  
8 experience --

9 THE COURT: Maybe I'm wrong, but I have not  
10 heard anything about his experience in front of the FDA. I  
11 have not heard anything about his knowledge of the  
12 regulations that govern ANDAs. I mean, I have not heard  
13 anything about that. Now, he may have it, but -- and was he  
14 proffered as an expert in that?

15 MR. HALES: He wasn't proffered as an expert in  
16 that, Your Honor. There was a time when some of that  
17 material was in some of his supplemental expert reports and  
18 it has been withdrawn. I don't think it's appropriate.

19 MR. LOEB: That's right, Your Honor.

20 THE COURT: Well, I know it's right. You're  
21 saying everything I said is right? I don't think so.

22 MR. LOEB: I thought you might have overheard  
23 Mr. Black. Sorry. He's testifying consistent with his  
24 reports that are not withdrawn.

25 MR. BLACK: And for which there was no Daubert.

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1 There's no Daubert on the testimony he's giving right now.

2 THE COURT: Right. And I mean -- well, I guess  
3 maybe this, part of me wants to say just let it come in,  
4 it's a bench trial. That's part of me. Part of me wants to  
5 say I didn't hear him -- I heard him offered as an expert in  
6 pharmaceuticals and I heard him define pharmaceuticals to talk  
7 about drug formulation. Essentially, the science of drug  
8 formulation.

9 It seems to me, and I've read some of these  
10 cases you both have talked about, we're in the realm of law,  
11 and, frankly, I think what we're really in is the realm of  
12 what the FDA would do.

13 MR. LOEB: Might I ask a few questions about  
14 this to Dr. Kirsch?

15 THE COURT: You can, sure.

16 BY MR. LOEB:

17 Q. Okay. Dr. Kirsch, are you familiar with the process  
18 of providing quality control information to FDA?

19 A. Yes. In my career as an industrial scientist and  
20 group leader, I was called upon to provide information and  
21 to interact with the FDA with regard to the product that I  
22 was responsible for.

23 I've also worked with FDA scientists in the  
24 review section and I've also put together training programs  
25 for FDA review scientists, so I have some level of

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1 experience with the FDA.

2 Q. All right.

3 THE COURT: Okay. Hold on.

4 MR. HALES: Now we're actually going into the  
5 material that wasn't disclosed in his report because that's  
6 the type of information that he was not proffered as an  
7 expert in.

8 I also agree with whatever points you've made,  
9 whatever experience he had, he's not here to speak to what  
10 the FDA will or will not allow. That's not his expertise.  
11 They did have a report and they did have an expert in the  
12 Amneal case that tried to do certain things, was proffered  
13 and tried to act as an FDA expert. That has never been done  
14 here. It's not appropriate.

15 MR. LOEB: Your Honor, just to be clear, Eagle  
16 is in the same boat here. Neither party has provided an  
17 expert that specifically designated --

18 THE COURT: I get that. The burden is on you.

19 MR. LOEB: Understood, Your Honor.

20 MR. BLACK: Your Honor, let me try to address  
21 this and cut down the middle a little bit.

22 There are certainly things about the  
23 interpretation of the regulation which would be -- would  
24 require a different kind of expert and that you're not going  
25 to hear in this case, but it's also true that those who work

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1 in drug development and work with the FDA as Dr. Kirsch had  
2 have some working knowledge of how these specifications are  
3 used.

4 Just like Dr. Aungst testified to, he's a person  
5 in the industry. He works in drug development. He has some  
6 level of knowledge. He should be able to answer the  
7 questions up to his level of knowledge.

8 We don't technically have to proffer a witness  
9 in a particular area. We did it that way as sort of a  
10 formality, but he had to have the expertise to answer each  
11 question, that's true, and I think it has been established  
12 that the question that was asked by Dr. -- he used to be a  
13 doctor before he became a lawyer and was demoted.

14 Mr. Loeb, it was appropriate for him to answer.  
15 Yes, familiarity with the specification and how the FDA  
16 process works. He doesn't have deep familiarity with, you  
17 know, esoterica of the FDA, but he has to testify on that.

18 And, more fundamentally, they did not object to  
19 this testimony, which is in his report. There has been no  
20 Daubert here. The time for Daubert is long passed. And to  
21 the extent there's something in his report that he can  
22 testify to, he should be permitted to do that and Your Honor  
23 can deal with this as a matter of credibility later if they  
24 want to make that argument in the post-trial briefing.

25 THE COURT: Well, I think the objection is it's

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1 not in his report.

2 MR. BLACK: No. Actually, I didn't hear that.

3 THE COURT: Oh, I did.

4 MR. HALES: I did say that.

5 THE COURT: That was exactly the last objection.

6 He said he didn't disclose it. Maybe you can tell me where  
7 in the report it is.

8 MR. LOEB: Certainly, Your Honor. I don't know  
9 if you've been provided with --

10 THE COURT: I have.

11 MR. LOEB: Okay. So starting with the  
12 infringement report, paragraph 55, so let me just see which  
13 one that is.

14 THE COURT: This is the opening report?

15 MR. LOEB: I'm just checking. Yes, Your Honor.  
16 Tab 1 in the binder.

17 THE COURT: All right. And page what did you  
18 say? I'm sorry.

19 MR. LOEB: Paragraph 65. I don't know a page  
20 yet.

21 THE COURT: Paragraph 65. I've got it.

22 MR. LOEB: Okay. So that refers to the release  
23 specifications and Eagle's compliance with them.

24 THE COURT: I would expect him to be able to  
25 testify about this.



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1 MR. LOEB: Okay.

2 THE COURT: This is a different question.

3 This is just as a matter of science, you know, may be  
4 drawing inferences from the stability data. Can you infer  
5 what would happen to the pH over the duration of the shelf  
6 life?

7 I think there's an absolute probably  
8 black-and-white answer about this and I have a kind of  
9 inclination as to what it is, but regardless of my  
10 inclination, which is I'm just trying to apply logic to the  
11 facts so far.

12 I think we know what I think if we bring in an  
13 FDA person here what they would say. This is what the  
14 release specification means, this is what the stability  
15 specification means. I think that would be pretty clear.  
16 That's what I'm kind of waiting for.

17 MR. LOEB: Understood, Your Honor. To address  
18 the last question, if you would turn to tab 2 in the binder.  
19 So this is the reply report for Dr. Kirsch on infringement.

20 And if you turn to paragraph 32, and you can  
21 just look at the, I think it's just the last sentence. It's  
22 very similar to the question that I just asked.

23 THE COURT: Mr. Hales, I'm going to allow the  
24 testimony to proceed based on the statement in paragraph 32.  
25 I think it raises questions. Well, I will allow it to go

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1 forward and you can see how the evidence comes in in its  
2 totality, and I would allow you to -- I will entertain if  
3 it's appropriate whether you want to renew this objection.

4 I'm not going to allow it in for right now, and  
5 because there's a sentence in here that says, "If FDA were  
6 to approve Eagle's ANDA, Eagle will be able to make and sell  
7 those batches with a 3.6 pH at release similar to SVA001."  
8 And that is in the report, so I think it's sufficient to  
9 constitute a disclosure about this testimony.

10 MR. HALES: That part I understand, Your Honor,  
11 coming in, the disclosure. I would note it's in the reply  
12 report. It's not the right time to be putting in an opinion  
13 on something --

14 THE COURT: Yes. But I mean it's in the report.  
15 There was a disclosure before trial.

16 MR. HALES: And it doesn't change the fact --

17 THE COURT: You made your objection. I think  
18 your only objection that's outstanding was the disclosure  
19 objection. Right?

20 MR. HALES: No, no. I think it calls for a  
21 legal question and he has got no expertise to speak to the  
22 FDA.

23 THE COURT: I'm going to allow that to proceed  
24 right now because it sounds like, you know, at least the  
25 way, what I infer from Mr. Black and maybe some of the

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1 things that have been said, maybe your expert is going to  
2 get into this realm, too. I don't know. I don't know how  
3 the evidence is going to come in. So we'll let it go.

4 MR. HALES: Yes. And just to be clear, our  
5 expert is not going to do that.

6 THE COURT: Okay. Well, let's see. To the  
7 extent that your argument is whether it's appropriate to  
8 have any kind of expert testimony, you also raise, well,  
9 Daubert motions. I don't recall a Daubert motion. Was  
10 there?

11 MR. HALES: The parties agreed not to do  
12 Daubert, but that doesn't prevent us from making the  
13 challenge.

14 THE COURT: Actually, I agree with that.  
15 That's a good point. In fact, I appreciate frankly the  
16 absence of Daubert motions because I would rather just rule  
17 on them when they come up so it's crystal clear.

18 I'm going to let the testimony proceed. I have  
19 a funny feeling we'll be revisiting the issue.

20 MR. HALES: Okay.

21 MR. LOEB: Thank you, Your Honor.

22 BY MR. LOEB:

23 Q. Dr. Kirsch, assuming FDA approves Eagle's ANDA as it  
24 stands currently, could Eagle release a commercial batch  
25 which is similar to SVA001?

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1 A. Yes.

2 Q. All right. Now, is the measured pH for SVA001, which  
3 was 3.7 and 3.8 at the 24-month time frame an anomaly?

4 A. No, it's not an anomaly. It is as described in the  
5 out-of-specification report, the result of the product.

6 Q. All right. I'd like to turn off the slide for a  
7 second and if you could just bring up PTX-1435 on the  
8 screen. There it is, page 10 of PTX-1435. So that's just  
9 the next page from where we're just looking.

10 What does Figure 1 from PTX-1435 show?

11 A. So this is a collection of the pH stability results  
12 for the three registration batches for SVA1, 2 and 3. The  
13 pH data for SVA1 are shown with the red open circles. The  
14 pH data for SVA2 are shown as green triangles and the pH  
15 data for SVA3 are shown as the inverted blue triangles.

16 Now, what one can see also on these plots or in  
17 this figure are trend lines. It's easiest to see if you  
18 look at the green line that corresponds to SVA2, and it  
19 shows the increase in pH over time of the -- of this  
20 particular registration batch.

21 The other thing which is shown on this figure  
22 are the confidence limits for the trend line, so this would  
23 be where one would expect the pH value, the measured pH  
24 values to fall 95 percent of the time as a function of time.

25 And if you look at, for example, the red shaded

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1 area, which corresponds to SVA1, you can see that that  
2 shaded area goes outside the -- the stability specification  
3 of 3.64 and into the claimed range somewhere around ten  
4 months.

5 Q. Might I stop you just for a second?

6 A. Sure.

7 Q. Just for clarity, looking at Figure 1, you mentioned  
8 the stability specification of 3.64. How is that shown on  
9 the figure?

10 A. So that is shown as the dotted line. There are two  
11 dotted lines that are on the figure. There's one at 3.64  
12 and the other one is at 3.35. These represent the upper  
13 bounds of the -- upper and lower bounds of the stability  
14 specification for pH.

15 Q. And I apologize if I interrupted your answer. You  
16 were talking about this pink shaded area, I think.

17 A. Right. So for SVA1, you can see the 95 percent  
18 confidence limit, the upper limit goes outside of the claim  
19 of the stability specification range and into the claimed  
20 range around ten months.

21 Moreover, if you look at the data for SVA3 and  
22 look at the estimated confidence limit for that data, you  
23 can see that that goes out outside the stability  
24 specification range and into the claimed range somewhere  
25 around 20 months or so.

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1                   So, you know, it shows that these pH values are  
2                   increasing with time and that they do -- the confidence  
3                   limits at least do extend outside the stability  
4                   specification.

5           Q.       Now, given Figure 1 from PTX-1435, which is the recent  
6                   stability summary, what can you conclude about the  
7                   likelihood that batches released at pH 3.64 or pH 3.63 or pH  
8                   3.62 or lower would have, or will have vials that exceed pH  
9                   3.65 at some point in their life?

10          A.       Well, I would conclude that this is a likely  
11                   occurrence, that these batches would have pH values outside  
12                   or within the claimed range.

13          Q.       And you mentioned SVA3. What was the release pH of  
14                   that particular registration batch?

15          A.       My recollection is that that value -- that the release  
16                   value there was at 3.60.

17          Q.       Did Eagle generate any other batches to support its  
18                   ANDA submission?

19          A.       Yes, they did.

20          Q.       Have you prepared a slide on that?

21          A.       Yes. Let's go to the next slide.

22          Q.       And what does this show?

23          A.       So they also, in addition to the three registration  
24                   batches 1, 2 and 3, they also prepared batches 4, 5 and 6,  
25                   which are the so-called characterization batches, and then

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1 7, 8 and 9, which are the optimization confirmation batch.

2 Q. All right. So now you've reproduced on your slide  
3 Table 1, Table 8 and Table 14 from PTX-1435; is that  
4 correct?

5 A. That's correct.

6 Q. Okay. And so that's the same document we've been  
7 looking at?

8 A. That's correct.

9 Q. The stability summary and conclusion.  
10 How does Eagle currently characterize its  
11 registration batch SVA001?

12 A. It describes it as a representative batch.

13 Q. And have you formed an opinion as to whether Eagle's  
14 registration batches SVA1, 2 and 3 are still representative  
15 of what Eagle would be authorized to release into the market  
16 if the FDA approved the ANDA?

17 A. Yes. I mean, you know, they state that this is a  
18 representative batch, so it would still be representative of  
19 the commercial product.

20 Q. Now, during Mr. Hales' opening statement, you heard  
21 that Eagle thinks that it fixed the problem with pH  
22 stability.

23 Do you agree with that?

24 A. No, I don't agree with that.

25 Q. And at any time has Eagle amended the release pH

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1 specification in order to get further away from the patent  
2 claims?

3 A. No. The release specification has remained at 3.4 to  
4 3.6.

5 Q. Now, has Eagle generated any additional batches of  
6 vasopressin that aren't mentioned in the recent stability  
7 summary and conclusion provided to FDA?

8 A. Yes. The next slide, I think there are eight  
9 additional batches -- 10, 11, 12, 13, 14, 15, 16 and 17.

10 Q. Okay. Were batches SVA7 through 17 made with the  
11 fixes that Mr. Hales was talking about during the opening?

12 A. Yes, they were.

13 Q. Okay. And do you believe that Eagle's pH now in its  
14 current process is well controlled based on the changes that  
15 it has made?

16 A. No, I don't believe that it is well controlled.

17 Q. All right. And why not?

18 A. Well, we can look at the data that we have for SVA11  
19 and we can look at the variability that we see with pH in  
20 that batch and I could see pretty good evidence of the type  
21 of variability that they will get in their measurement.

22 Q. All right. Now, did you have any of that data when  
23 you provided your original opinion in your opening and reply  
24 report?

25 A. No, I did not.



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1 Q. So you mentioned SVA11. Let's look at PTX-1235 in  
2 your binder. If you can tell me what that is.

3 A. So this PTX-1235 is the process performance  
4 qualification protocol or SVA11.

5 Q. Okay. And did you watch the video of Eagle's  
6 corporate designee, Dr. Aungst, a little while ago?

7 A. Yes, I did.

8 Q. All right. And how does Dr. Aungst's testimony relate  
9 to the SVA11 manufacturing testing?

10 A. Well, I mean, he describes this as -- as appropriate,  
11 valid testing.

12 Q. And what -- if I could go down the slide, we have some  
13 blowup from PTX-1235.

14 What did Eagle express as the purpose for making  
15 SVA11?

16 A. Well, they -- they said that the purpose is to provide  
17 documented evidence about the manufacturing process and  
18 consistently through the product meeting, the specification.

19 Q. And you're reading from the Bates number ending at 370  
20 from PTX-1235?

21 A. Correct.

22 Q. Okay. And how does the manufacturing process for  
23 SVA11 compare to Eagle's current protocol for manufacturing  
24 batches?

25 A. So it's the same process. In the process performance

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1       qualification, they do additional testing, so in the  
2       commercial batches, for example, they would only do one  
3       release test and at least for SVA11, they did six release  
4       tests, but the process that they use is the same.

5       Q.       Okay. So what's the commercial batch size for Eagle's  
6       product?

7       A.       I think the intended commercial batch size is  
8       35 liters, which corresponds to 25 -- over 25,000 vials.

9       Q.       And you've reproduced the size of the batch and the  
10      vial numbers from page 382?

11      A.       Correct.

12      Q.       And have you reviewed Eagle's -- well, let me ask you  
13      this first: What did Aungst -- Dr. Aungst, excuse me,  
14      testify about whether each pH test result that was conducted  
15      on SVA11 were valid or not?

16      A.       He testified that they were valid measurements.

17      Q.       And have you reviewed the actual data from the SVA11  
18      testing?

19      A.       Yes, I have.

20      Q.       All right. And have you prepared a slide showing the  
21      relevant data?

22      A.       Yes. Go to the next slide.

23                       So this is a collection of the pH result from --  
24      for SVA11. They did a couple of in process measurements.  
25      The first one was the so-called pre-filtration measurement.

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1 This was a measurement that they made on the bulk solution  
2 before it was filled in and then they make a post-filtration  
3 measurement using five vials from the first 300 vials that  
4 were filled.

5 And then -- so those are the in-process testing  
6 results and they got pH measurements of 3.50 and 3.50. And  
7 then they selected vials from the beginning of the filling  
8 run and then from the middle of the filling run and also  
9 vials from the end of the filling run and did pH testing on  
10 those vials as well. And you can see that in the beginning,  
11 they got pH values of 3.54 and 3.51. In the middle they got  
12 values of 3.56 and 3.49. And then from the end vials, they  
13 got values of 3.57 to 3.47.

14 So you can see that there was variability in the  
15 values that they got in release testing and they varied by  
16 as much as a tenth of a pH unit, 3.47 to 3.57, and they also  
17 varied from the in process testing as well. So the  
18 in-process test values that they got were different than a  
19 number of the release testing values that they got.

20 Q. All right. Were the vials tested for SVA11 in each of  
21 these tests shown here on your demonstrative number 34  
22 pooled in groups of five like you explained earlier?

23 A. Yes. Each of those tests represents a collection of  
24 five vials that they -- that they combined in order to make  
25 the pH measurement.

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1 Q. Okay. And given that the vials were pooled, could the  
2 actual variation between Eagle's vials be greater than what  
3 was in the literature?

4 A. Yes.

5 Q. Okay. And how did the testing of the in process  
6 post-filtration compare to the testing at release?

7 A. So, again, the post filtration test, the in-process  
8 test was 3.50. Then they got a range of values for release  
9 testing that were higher and some that were lower than the,  
10 than the -- than both filtration values.

11 Q. So just to get a sense of it, were these tests all --  
12 excuse me, were the vials all filled on the same day?

13 A. Yes. I mean, filling operation is completed within a  
14 day and, you know, the post-filtration end process test that  
15 they got was 3.50 and then they got release testing values  
16 as high as 3.57, so there's seven-hundredths of pH of a  
17 difference between what they got at least one time between  
18 the in-process and the -- and the release test.

19 Q. Could you elaborate on what the pH variability  
20 observed for SVA11 would tell us about the variability  
21 within all the vials in other batches of Eagle's  
22 vasopressin?

23 A. So you would expect to see the same type of  
24 variability. You could -- this is an example where they  
25 have seen differences in their pH measurements of a tenth

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1 of a pH unit and so that wouldn't be necessarily unexpected.

2 Q. Okay. Now, why is it that you focus on SVA11 as  
3 opposed to the other batches between SVA7 and 17?

4 A. Well, this is the one that had the most replicates,  
5 release test values. This had six values. In other words,  
6 it gives us a pretty good idea of how variable the pH  
7 measurement can be.

8 Q. Given these data for SVA11, would you consider Eagle's  
9 manufacturing process well controlled for pH?

10 A. No. You know, I think that clearly, there's a  
11 significant variability of the measured pH and there's  
12 differences between the measured pH in-process and that at  
13 release. I mean, if you look at these just in a very sort  
14 of simple way and imagine that, for example, they had an  
15 in-process test at 3.54, which would be the upper limit of  
16 what the in-process test is allowed to be according to their  
17 new guide, new manufacturing rule.

18 You know, if they were to get a pH result at  
19 release that was five-hundredths greater, that would be a  
20 result of 3.61. Now, that would still meet their release  
21 testing specifications, but now it's getting into the upper  
22 end of the release pH specification.

23 Q. So based on what you just said, would you expect the  
24 release pH for a commercial batch to be the same as the pH  
25 measured during the in-process testing?

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1 A. Not necessarily.

2 Q. And based on your understanding of the ANDA  
3 documentation, will Eagle generate any data that will be  
4 sufficient to assess the variability of its commercial  
5 batches assuming the ANDA is approved?

6 A. No, because they're not making multiple tests  
7 released. They are making a single test.

8 Q. All right. Now, Eagle's expert, Dr. Park, will opine,  
9 we expect, that by tightening the in-process pH  
10 specification to a maximum of 3.54 pH, Eagle has prevented  
11 any future product from reaching the claimed pH range.

12 Do you agree with that?

13 A. No, I don't agree. As I just mentioned, I mean, if  
14 they release something at the upper end, I mean, if they  
15 measured an in-process test at the upper end of their range,  
16 3.54, they, according to these data, and this is the only  
17 data that we really have to show variability, they could  
18 have a value as high as 3.61, for example, and that would  
19 be, that would be at the upper range of their release pH  
20 range and could well result in vials that by the end of  
21 expiry were within the claimed range.

22 THE COURT: All right. Hold up.

23 MR. HALES: Yes, I'm sorry. It wasn't clear  
24 that was going to come out, Your Honor, but I don't think  
25 there's any disclosed opinion that that value 3.61 is going

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1 to end up having variability outside the claim range, in the  
2 claim range, in the claim range.

3 MR. LOEB: Just a moment, Your Honor.

4 THE COURT: Sure.

5 MR. LOEB: Your Honor, I direct you to tab 4 in  
6 Dr. Kirsch's reports binder, which is the second  
7 supplemental expert report, and in particular paragraph 14.  
8 And just to try to zoom you in on the relevant portion, this  
9 is on the -- on page 10 it says --

10 THE COURT: Actually, hold up. Paragraph 14?

11 MR. LOEB: Paragraph 14, page 10.

12 THE COURT: Yes. Mr. Hales, do you want to look  
13 at that? I think it's a typical disclosure.

14 MR. HALES: Sorry.

15 THE COURT: I think that disclosure would cover  
16 it. It can be as high as 3.64. He was talking about --

17 MR. LOEB: Actually, Your Honor, it says,  
18 indeed, lower pH values within the release specification.

19 THE COURT: Right. But I guess my point was  
20 whether he said it, I thought the point is that you can have  
21 the in-process and you can get a higher rate and there's  
22 variability. I mean, that's generically.

23 MR. HALES: I thought the question was a  
24 different one, Your Honor, which is he was saying that at a  
25 value of as low as 3.61, there is drift, there will be drift

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1 into the claimed range.

2 THE COURT: I think he said that based on, there  
3 will be drift -- the way I interpreted it was that we were  
4 focused on the -- was it post-filtration? Hold on a second.

5 The process specification of a maximum of 3.54  
6 pH was the focus of the question, and based on that, have  
7 they presented any future products from reaching the claimed  
8 pH range. So the starting point would be from 3.54 pH.  
9 Right? There would be variability.

10 MR. HALES: Your Honor, I don't have the  
11 LiveNote in front of me, but I thought I was asking about  
12 the release specification, not the process.

13 THE COURT: Okay. Hold on. I was focused on  
14 the question before. That's my problem.

15 So here is the question. Dr. Park will opine,  
16 we expect, that by tightening the in processing pH  
17 specification to a maximum of 3.54 pH, Eagle has prevented  
18 any future product from reaching the claimed pH range.

19 So that's where they're focusing on. The in  
20 process training and the 3.54. He is basically saying  
21 there's variability from that, it will go up.

22 The objection right away -- it wasn't right  
23 away. You finished the question. Mr. Hales stood up and I  
24 asked you to hold up.

25 Mr. Hales said it wasn't clear it was going to



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1     come out, but I don't think there's any disclosed opinion  
2     that the value of 3.61 is going to end up having variability  
3     outside the claimed range.

4             I guess that is a little bit -- well, I guess  
5     then I'm confused by the objection, because I thought the  
6     whole point of the question was the in-processing pH  
7     limitation allows them to get to 3.54, which because of  
8     variability can creep up to 3.61.

9             He already testified, I thought an interesting  
10    question I might come back to, but basically I understood  
11    there's an opinion question such that, well, assuming we're  
12    at the upper end of the range, which might be, and I think  
13    the question was 3.64, 3.63, 3.62 3.61, what would happen,  
14    and he said that would cause infringement. I thought that's  
15    where he's drawing the linkage to that from that in-process  
16    testing, 3.54 limitation to the prior opinion statement. So  
17    I don't actually understand your objection, Mr. Hales.

18            MR. HALES: I think it's clear that they have  
19    said that with the in-process specification of 3.54 and what  
20    Dr. Kirsch calls variability, that that would allow the  
21    release to go all the way up to 3.64.

22            And then he said --

23            THE COURT: His opinion is a little bit more  
24    flexible. It can be 3.61 if we're going to get into the  
25    territory of drift. That's what I understood.

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1 MR. HALES: That's the part --

2 THE COURT: That was asked a long time ago and  
3 came into evidence.

4 MR. HALES: Not that 3.61 would then drift into  
5 the --

6 THE COURT: I think it was. In fact, I wrote it  
7 down. I'm pretty sure.

8 Hold on a second. Actually, I'm off by a  
9 number. The question says, "Now, given Figure 1, which is  
10 the recent stability summary, what can you conclude about if  
11 likelihood that batches released at pH 3.64 or pH 3.63 or pH  
12 3.62 or lower would have or will have that exceed pH 3.65 at  
13 some point in their life?"

14 He concludes, "I think this is a likely  
15 occurrence that these batches would have pH values outside  
16 or within the claimed range."

17 You didn't object to that.

18 MR. HALES: Yes. I don't remember the context  
19 of that now, Your Honor, but I will help you with it on  
20 cross or through our expert.

21 MR. LOEB: May I continue?

22 THE COURT: Yes.

23 BY MR. LOEB:

24 Q. If Eagle follows its protocol and releases a batch  
25 with a reported release value of 3.64 or indeed lower pH

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1 values within the release specification, is it more likely  
2 than not that many of the vials within the batch would have  
3 a pH value of 3.65 or higher at release?

4 A. Yes.

5 Q. Any doubt the question again, because I misspoke  
6 slightly.

7 The same question. If you -- if Eagle follows  
8 its protocol and releases a batch with a recorded release pH  
9 of 3.64 or indeed lower value within the release  
10 specification, is it more likely than not that many of the  
11 vials of the batch would have would have pH values at or  
12 above 3.64 at some point during their shelf life?

13 A. Yes.

14 Q. Now, have you prepared a slide summarizing your  
15 opinion as to whether or not Eagle will directly infringe  
16 '785, claim 1?

17 A. Yes, I have. Let's look at the next slide.

18 So there again, there were four elements in  
19 claim 1 and the first three elements were stipulated, so  
20 the issue centers on the pH requirement, the pH, wherein the  
21 unit dosage form has a pH of 3.7 to 3.9, and it's my opinion  
22 that if Eagle's product is released at the upper end of this  
23 pH range, that it will infringe this element of the claim.

24 Q. Okay. And so if FDA approves the ANDA as it currently  
25 exists, would Eagle be authorized to sell products during

Kirsch - direct

1     their shelf life that are more likely than not to infringe  
2     claim 1 of the '785 patent?

3     A.     Yes.

4     Q.     All right. And why do you say that?

5     A.     Well, I say that because we have seen evidence of that  
6     happening, so there's direct evidence that the pH can get  
7     within the claimed range.

8     Q.     All right. Now, what is your conclusion as to whether  
9     or not Eagle's ANDA product will directly infringe claim 5  
10    and 8 of the '785 patent?

11    A.     So let's go to the next slide.

12                 So all of those claims, 5 and 8, depend upon  
13    claim 1 and, you know, I've expressed that pH limitation of  
14    claim 1, and there are no additional requirements for claim  
15    5 and 8 except those that have already been stipulated.  
16    Therefore, Eagle will infringe claims 5 and 8 of the '785  
17    patent as well.

18    Q.     Okay. So just to be clear, you're not saying that  
19    every batch that Eagle would be authorized to make would  
20    infringe, are you?

21    A.     No, I'm not. I'm saying that if they release batches,  
22    you know, within their release specification, but at the  
23    upper end of that release specification, that they are  
24    likely to infringe.

25    Q.     So if FDA approves Eagle's ANDA, would Eagle be

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1 authorized to sell products during their shelf life that are  
2 more likely than not to infringe claims 5 and 8 of the '785?

3 A. Yes.

4 Q. Okay. And now I'd like to ask you about whether the  
5 use and sale of Eagle's ANDA product will satisfy the  
6 limitations of claim 1 of the '209 patent.

7 Do you have a slide on that?

8 A. Yes. Let's go to the next slide.

9 Q. What's your position?

10 A. So these are the elements of claim 1 of the '209  
11 patent and all of those elements have been stipulated to  
12 except for the pH claim, the unit dosage form has a pH  
13 of 3.7 to 3.9, and that's the element that I've been  
14 addressing, so I believe that that element will be -- will  
15 be infringed as well.

16 Q. So if FDA approves Eagle's ANDA in its current form,  
17 would Eagle be authorized to sell products that during their  
18 shelf life are more likely than not to satisfy the  
19 limitations of claim 1 of the '209 patent?

20 A. Yes.

21 Q. All right. And why is that?

22 A. Well, again, because if Eagle releases product at the  
23 upper range of the pH specification, they are likely to  
24 infringe the pH claim or pH element of claim 1 and therefore  
25 they will infringe.

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1 Q. Okay. Now, what is your conclusion as to whether or  
2 not the use and sale of Eagle's ANDA product will satisfy  
3 the limitations of claims 4, 5 and 7 of the '209 patent?

4 A. So let's go to the next slide.

5 So, once again, using the same logic as before,  
6 demonstrating that they will infringe claim 1, the pH  
7 limitation of claim 1, there are no additional elements of  
8 claims 4, 5 and 7 except those that have been stipulated to,  
9 so they will infringe the dependent claims 4, 5 and 7 as  
10 well.

11 Q. So if FDA approves Eagle's ANDA, would Eagle be  
12 authorized to sell products that during their shelf life are  
13 more likely than not to satisfy the limitations of claim 4,  
14 5 and 7 of the '209 patent?

15 A. Yes.

16 Q. All right. And do you have an opinion as to whether  
17 Eagle will induce infringement of the '785 patent claims 1,  
18 5 and 8?

19 A. Sure. Let's go to the next slide.

20 So, again, the expiry period, the recommended  
21 expiry period is 24 months at refrigeration. So their  
22 product can be used within that shelf life, and you've seen  
23 evidence that if they release the product at the upper range  
24 of pH specification, that the product can go into the  
25 claimed range and Eagle is aware of this.

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1                   They're instructing clinicians to use the  
2                   product within its shelf life and stored at refrigeration  
3                   and therefore they're inducing the users of their product to  
4                   infringe.

5           Q.       All right. Now, you've reproduced some documents  
6                   here. The first one is the stability summary, 1435, that  
7                   we've already looked at. What is that page?

8           A.       I'm sorry. I didn't catch your question.

9           Q.       Yes. You've highlighted part of the stability summary  
10                   regarding the expiry period and I am asking what that is?

11          A.       So that is the expiry period, 24 months at a storage  
12                   temperature of two to eight, which is controlled  
13                   refrigeration.

14          Q.       All right. And then the document that you've  
15                   reproduced below is PTX-1417. What is that document?

16          A.       So this is from the package insert for Eagle's ANDA  
17                   product.

18          Q.       And what is the portion you've highlighted there?

19          A.       So the portion I've highlighted again is the -- the  
20                   instructions for storage of their product.

21          Q.       All right. Now, do you have an opinion as to whether  
22                   Eagle will induce its customers to use its product in such a  
23                   way that they will meet the formulated -- formulation  
24                   related limitations of the '209, claims 1, 4, 5 and 7?

25          A.       Yes. It's my opinion that they will induce

Kirsch - direct

1 infringement for those batches that are released at the  
2 upper end of the pH specification and those batches will  
3 infringe and therefore they will be inducing infringement.

4 Q. Could we -- first of all, could you look at PTX-1417  
5 in your binder? Could you identify what that is, please?

6 A. So this is the packaging information, the prescribing  
7 information for Eagle's ANDA product.

8 Q. Okay. Can I have you, please, turn to the page that  
9 ends in 906, please?

10 MR. LOEB: Would it be possible to put 1417 up?  
11 In particular, the page ending in 906.

12 BY MR. LOEB:

13 Q. Okay. I would like to draw your attention to the last  
14 section on page 906. This is 11, description. And there's  
15 a sentence at the very bottom of the page that says, the one  
16 ml solution contains vasopressin 20 units per ml  
17 chlorobutanol NF 0.5 percent as a preservative and water for  
18 injection, USP adjusted with acetic acid to pH 3.4-3.6.

19 Could you explain what the significance of this  
20 passage in Eagle's proposed labeling that says adjust with a  
21 acetic acid of pH 3.4 to 3.6?

22 A. Well, it means that in the compounding of their  
23 formulation, it gives the unit dose, the unit formula, and  
24 it's saying that they adjust that -- that product to a pH of  
25 between 3.4 and 3.6.



Kirsch - direct

1 Q. Is there any reference made to the in process  
2 specifications for Eagle's ANDA product in the label, which  
3 is PTX-1417?

4 A. No. I mean, they're not providing the specification  
5 for the product. They are simply saying that they adjust  
6 it, they adjust the product to a particular pH. You know,  
7 there are some products where you see that have a particular  
8 pH value, so it could be that they adjust it to some pH,  
9 like pH 3.5.

10 MR. LOEB: Thank you, Dr. Kirsch. I have no  
11 further questions. I would like to move in a few documents.

12 THE COURT: Okay.

13 MR. LOEB: JTX-3, PTX-53, PTX-208, PTX-1353,  
14 PTX-1427 and PTX-1435.

15 MR. HALES: No objection.

16 THE COURT: All right. They're moved.

17 (JTX-3, PTX-53, PTX-208, PTX-1353, PTX-1427 and  
18 PTX-1435 were admitted evidence.)

19 THE COURT: Do you want to take a break for a  
20 second?

21 THE WITNESS: Sure.

22 THE COURT: You can step down, hit the restroom.

23 THE WITNESS: Okay.

24 THE COURT: Then ten minutes? I would like to  
25 move it. How much time do you need?

1 MR. BLACK: Ten minutes would be fine, Your  
2 Honor.

3 MR. HALES: Ten minutes is fine, Your Honor.

4 THE COURT: I was wondering if you want less.  
5 You want at least ten?

6 MR. BLACK: I think we could use -- we've been  
7 pretty good today. He's our last witness. Then we're going  
8 to rest and we'll be into their case shortly.

9 THE COURT: Okay. Let's do ten minutes and  
10 we'll pick up right away. Let's come back at 20 of.

11 (Short recess taken.)

12 - - -

13 (Proceedings resumed after the short recess.)

14 THE COURT: Please be seated.

15 MR. HALES: We're getting some binders to hand  
16 up to Your Honor.

17 THE COURT: Okay.

18 MR. HALES: And also if I were going to use a  
19 board with the witness, how would you want me -- how could I  
20 do that? Put it over here?

21 THE COURT: Well, you can't block them.

22 MR. HALES: I know. I don't know if you have an  
23 approach you usually take. I could put it in the back  
24 corner, I guess.

25 THE COURT: I guess I would have to see the

1 board. Are you going to bring up your --

2 MR. HALES: It's the demonstratives, the two  
3 that you saw earlier, yes.

4 THE COURT: I'm comfortable with it up there.  
5 What do you think?

6 MR. BLACK:

7 MR. LOEB: Your Honor, as long as we're sure  
8 it's the same thing they are going to provide me.

9 THE COURT: It's going to be what he put up in  
10 opening, so that's fine, so you know it's coming.

11 MS. WACKER: Is that okay if we bring it over  
12 here?

13 THE COURT: Yes.

14 MS. WACKER: Thank you.

15 THE COURT: Actually, you know what, here's what  
16 we'll do. We'll just stick it in the jury box. Now let's  
17 make sure the witness can see it.

18 All right. Can you see that, sir?

19 THE WITNESS: Yes.

20 THE COURT: But they can't. That's the problem.

21 MR. HALES: I mean, they have it.

22 MS. WACKER: We had it in our opening.

23 THE COURT: I don't know if you are going to  
24 point at it.

25 MR. HALES: In fairness, I probably will.

1 MR. LOEB: I'm not okay with that.

2 THE COURT: My law clerk can go back. Where  
3 you're standing is where the chart will go. When he  
4 cross-examines, you're just going to go to move. Okay?

5 MR. LOEB: Yes, Your Honor.

6 THE COURT: It's not a perfect setup, I agree.

7 I don't know if the witness can read it. Can  
8 you read it?

9 THE WITNESS: I can't read that.

10 THE COURT: We may not be able to use some of  
11 these.

12 MR. HALES: We can use it on the screen.

13 THE COURT: Frankly, it is so hard to read it,  
14 it's so big, I would suggest put it on the screen and you  
15 just get your IP person to focus in on it.

16 MR. HALES: Yes.

17 THE COURT: And have a hard copy that the  
18 witness and the lawyers can refer to.

19 MR. HALES: I don't know if it's do-able here  
20 even with a smaller one.

21 THE COURT: Okay. Let's just start.

22 MR. HALES: Okay. If I may, Your Honor, I will  
23 have Mr. Lasky hand them up.

24 THE COURT: Yes. Let's go ahead.

25 CROSS-EXAMINATION

Kirsch - cross

1 BY MR. HALES:

2 Q. Good afternoon, Dr. Kirsch.

3 A. Good afternoon.

4 Q. My name is Bryan Hales. Nice to meet you.

5 A couple quick questions. You have -- in your  
6 career prior to this, you didn't work with vasopressin; is  
7 that correct?

8 A. I have not worked with vasopressin.

9 Q. So of the literature that you published, it doesn't  
10 have anything to do -- you didn't write anything about  
11 vasopressin; is that right?

12 A. Not about vasopressin. Other peptides.

13 Q. Now, you -- let's -- in the documents that you've  
14 looked at, you understand, I think, right, that SVA1 was  
15 manufactured by AMRI when Eagle was not involved in the  
16 project; is that right?

17 A. That's what I heard this morning.

18 Q. And have you seen -- you've seen that in the evidence  
19 that you saw?

20 A. I don't recall.

21 Q. Let's pull up DTX-288, and you should have that in  
22 your cross binder.

23 A. Okay.

24 Q. And it's either up here or on your screen as well. So  
25 DTX-288 is the data collection form for SVA1; is that

Kirsch - cross

1 correct?

2 A. Yes, that's correct.

3 Q. All right. And that was, SVA1 was manufactured on  
4 March 3rd of 2017; is that correct?

5 A. Yes, correct.

6 Q. This is by OSO, which is related to AMRI I think you  
7 understand; right?

8 A. Yes.

9 Q. You see the customer there, that is indicated there on  
10 the OSO form is Sagent Pharmaceuticals in the upper right?

11 A. I see is that.

12 Q. You have not seen evidence that Eagle was involved in  
13 this point in time?

14 A. I have not seen any evidence.

15 Q. Do you know, you know when the patent issued in --  
16 sorry, in -- well, let's just bring it up?

17 THE COURT: I think it's September.

18 BY MR. HALES:

19 Q. Yes, September and August of 2017. That's after SVA1  
20 was made; is that correct?

21 A. Correct.

22 Q. I think both patents published in June of 2017; is  
23 that correct?

24 A. I'm sorry. Say it again.

25 Q. They were -- let's pull up JTX-2 and the cover. And

Kirsch - cross

1       there's an upper left of -- there's a publication, line 65.

2       There you go. See prior publication data?

3       A.     Yes.

4       Q.     June 8th of 2017?

5       A.     Correct.

6       Q.     Okay. You have not seen any evidence that either of  
7       the patents were published or their applications earlier  
8       than June of 2017, have you?

9       A.     No, no.

10      Q.     You've not seen any?

11      A.     No, I have not.

12      Q.     Now, if we go back to DTX-288 quickly and look at  
13      the -- if you highlight the second row, the pH  
14      specification, do you see that?

15      A.     Yes.

16      Q.     All right. So, and you see that when SVA1 was  
17      manufactured, the pH specification that was used was 2.5 to  
18      4.5 for release in shelf stability.

19                   Do you see that?

20      A.     I do.

21      Q.     Okay. Now, at that time -- and the result indicated  
22      there was 3.6 as you see; correct?

23      A.     Correct.

24      Q.     So at the time you would agree that the specification  
25      that AMRI was using was broader than the one that is in

Kirsch - cross

1 place today. Fair?

2 A. Yes, that's correct.

3 Q. And if we look also, if you go down lower on the --  
4 no. Sorry. Let's go to DTX-30 -- sorry, 319. 319. Okay.  
5 And then specifically, to page 357 of this.

6 MR. LOEB: What page ending?

7 MR. HALES: 357. Sorry.

8 BY MR. HALES:

9 Q. So DTX-319 is the certificate of analysis for SVA001;  
10 is that correct?

11 A. Yes, that's correct.

12 Q. Okay. And if we can blow out now, go down a little  
13 bit further, the pH again, second row. Yes, that's fine.  
14 You see the pH. Again, it's indicated that the  
15 specification was 2.5 to 4.5; is that correct?

16 A. Correct.

17 Q. And the target was 3.4 to 3.6; right?

18 A. That's correct.

19 Q. And again that's broader than the specification that  
20 exists for the proposed ANDA product today?

21 A. For, I'm sorry, which specification?

22 Q. Okay. Yes?

23 A. The release specification 3.4 to 3.6.

24 Q. Yes. What I'm talking about though, sorry. Do you  
25 see on the right you're talking about pre-filtration and



Kirsch - cross

1 post-filtration?

2 Do you see that?

3 A. Yes.

4 Q. Okay. And you see that the pre-filtration, right,  
5 this is -- pre-filtration happens during the manufacturing  
6 process; is that correct?

7 A. That's correct.

8 Q. And as does the post-filtration measurement?

9 A. My understanding is the post-filtration -- and I don't  
10 know about this particular batch, but as I understand it  
11 currently, the post-filtration measurements are taken on  
12 filled vials.

13 Q. And so this particular batch we're talking about is  
14 SVA1; is that correct?

15 A. Correct.

16 Q. So the pre-filtration measurement, right, was 3.7 for  
17 SVA1.

18 Do you see that?

19 A. Yes.

20 Q. Okay. And at the time, that was within the  
21 specification for pH for SVA1 manufacturing process; is that  
22 correct?

23 A. So I'm not sure what the specification was for  
24 pre-filtration. I'm sorry. I just don't see that on this  
25 form. It says that it conformed.

Kirsch - cross

1 Q. Well, the indication there was that a pre-filtration  
2 measurement of 3.7 for SVA1 was a conforming measurement;  
3 correct?

4 A. That's correct.

5 Q. And you don't have any evidence that would suggest  
6 that was a non-conforming value; is that correct?

7 A. No, I don't.

8 Q. Now, you've put up -- just a quick question here. I  
9 think your slide was your logarithmic scale slide. Do you  
10 recall that slide you used in the opening?

11 A. Yes.

12 Q. Slide 9.

13 MR. HALES: Could we put up slide 9 from Dr.  
14 Kirsch's direct examination slide?

15 BY MR. HALES:

16 Q. One thing I wanted to clarify, I don't know if you  
17 know this number or not, but would you agree that if you --  
18 and this 26 percent and 58 percent numbers, those are  
19 talking about the concentration of the hydronium ions; is  
20 that correct?

21 A. Right.

22 Q. Now, in the correspondence back and forth with the FDA  
23 that we're talking about in this case, people talk in terms  
24 of pH; is that right?

25 A. That's correct.

Kirsch - cross

1 Q. Right. So you don't see people talking about how  
2 their stability varied in relation to hydronium ions;  
3 correct?

4 A. I'm sorry. People? I mean, certainly, scientists  
5 talk about the way in which the instability occurs as a  
6 function of acid concentration.

7 Q. Right. And the correspondence back and forth with the  
8 FDA we've seen between the parties in this case, that's  
9 talked about in terms of pH?

10 A. Yes, they refer to pH.

11 Q. Now, your view of the claims as you explained is that  
12 the boundary of infringement or noninfringement is 3.65  
13 versus 3.64; is that correct?

14 A. Correct.

15 Q. And so if you were to look at the difference in  
16 percentage of hydronium ions for 3.65 or 3.64, that's down  
17 closer to two percent or two-and-a-half percent; is that  
18 fair?

19 A. I think that's correct, yes. Two percent,  
20 two-and-a-half percent.

21 Q. Now, you also talked about pooling of vials on your  
22 direct exam.

23 A. That's correct.

24 Q. Now, pooling of vials, that's standard procedure in  
25 the industry; is that right?

Kirsch - cross

1 A. Yes. It's typical for pH measurements based on the  
2 equipment that they have, whether they have micro probes  
3 that can measure in a single vial or whether or not they  
4 have larger probes that require more volume.

5 Q. One of the reasons it's done I think you're alluding  
6 to is because very often the probe is too big to either fit  
7 into a one millimeter vial or there's just not enough volume  
8 of liquid in a one ml vial to do the pH test; right?

9 A. Right. Well, it's not, you know, technically  
10 impossible, but it's typical, I think, that they would pool  
11 samples for pH measurements based on the equipment that they  
12 use.

13 Q. Right. That's something you have seen that Par does  
14 as well, I take it?

15 A. Yes. I'm not exactly sure how Par does their  
16 measurement, how many vials they use.

17 Q. But you would expect that they're probably pooling for  
18 pH measurement?

19 A. It's conceivable.

20 Q. Now, during your direct exam, you said, I tried to  
21 write it down, but I think you said that Eagle is still  
22 telling the FDA that batches 1 through 3 are representative  
23 of the pH of their product.

24 Does that sound about right? I don't have a  
25 transcript in front of me?

Kirsch - cross

1 A. Yes. I was referring to how they label their, their  
2 description of the registration batches in their latest  
3 submission of the stability summary. It says in that table  
4 that it's a representative batch.

5 Q. Could we pull that up? I think that was PTX-1433.  
6 Let's pull that up and go to page 4 or the page ending in  
7 589.

8 I think this is what you were -- if you look up  
9 just the middle one, there you go. I think this Table 1 is  
10 what you were pointing to when you made that, when you gave  
11 that testimony. Is that right, sir?

12 A. Yes, that's correct.

13 Q. All right. And so I think you were using that table,  
14 if I have it right, to say that Eagle is telling the FDA  
15 that batch, batch 1, batches 1 through 3 are representative  
16 of the pH of Eagle's proposed ANDA product. This is what  
17 you were talking about?

18 A. I think I was simply saying that they have represented  
19 that this batch is representative.

20 Q. Well, I'm sorry. I cut you off. Yes. Well, to be  
21 clear, it doesn't say in this, where it has the word  
22 representative there, it doesn't say it's representative,  
23 these batches, of the pH of the proposed product; is that  
24 correct?

25 A. It doesn't specifically mention pH in that -- in that,

Kirsch - cross

1 in that title, no.

2 Q. What it says is it's giving some representative batch  
3 information for the registration batches; is that correct?

4 A. That's exactly what it says.

5 Q. All right. And, in fact, you know that the  
6 manufacturing process in terms of pH and the processing and  
7 the in-process specification have been changed in relation  
8 to the development of the proposed ANDA product; is that  
9 correct?

10 A. There have been changes made.

11 Q. As compared to SVA1 to 3?

12 A. Yes. I understand that, but they have not explained  
13 that this is not a representative batch.

14 Q. Well, in fact, let's take a look at page ending in  
15 1574. There you go. And this is a section of this exhibit  
16 that you were talking about during some of your direct exam  
17 testimony; right?

18 A. Yes, that's correct.

19 Q. And this is the section where there's a discussion of  
20 the out-of-specification measurement for SVA1; right?

21 A. Correct.

22 Q. And I think if I remember, you highlighted a few  
23 sentences in here and you talked about those sentences, but  
24 one of them you didn't talk about is the final sentence of  
25 this. Let's take a look at that.

Kirsch - cross

1                   In that sentence they tell the FDA, in order to  
2                   provide greater confirmation of consistent product quality  
3                   through the proposed expiry period, the manufacturing  
4                   in-process controls were subsequently optimized to assure  
5                   tighter control of pH is maintained during manufacturing.

6                   Do you see that?

7           A.       Yes.

8           Q.       And then they refer the FDA to Section 3.2.P.3.3 for  
9                   further details on manufacturing process optimization; is  
10                  that correct?

11          A.       Correct.

12          Q.       So they've told the FDA that there are optimization  
13                   changes aimed at controlling pH more tightly to ensure that  
14                   it maintains pH throughout the shelf life as well; is that  
15                   correct?

16          A.       Well, they are talking about control. Yes, that's  
17                   correct.

18          Q.       All right. And then let's take a look at page 25, the  
19                   one ending in 590, up at the top on paragraph 3.

20                   So in paragraph 3, I don't think this is one  
21                   that you discussed during your examination, but this relates  
22                   to the optimization and confirmation batches that were  
23                   submitted to the FDA.

24                   Do you understand that?

25          A.       Yes, I do understand that.

Kirsch - cross

1 Q. Okay. And those are SVA7 through 9; is that right?

2 A. Correct.

3 Q. Okay. Those optimization batches are 7 through 9.

4 So in the first sentence they say, as discussed  
5 above, once the batch and aggregate available stability data  
6 were critically evaluated, it was recognized that despite  
7 the consistently within specification stability results  
8 obtained on most parameters stored under the basic label  
9 storage conditions, the process could be optimized further  
10 for better control of finished product quality.

11 Correct?

12 A. Yes, that's what it says.

13 Q. And then it says, specifically, the pH adjustment  
14 steps in the batch record were optimized for better control  
15 of the batch pH to the middle of the pH specification (i.e.  
16 3.50).

17 Do you see that?

18 A. Yes.

19 Q. So they told the FDA that the optimizations that were  
20 done were to improve pH and have better control of the  
21 batch, the middle of the pH specification; correct?

22 A. Yes. That's what that -- that's what that passage  
23 says.

24 Q. Right. And then if we look at the paragraph below --  
25 sorry, the small three-line paragraph right below there.



Kirsch - cross

1                   Now, clearly, they are not telling the FDA in  
2                   this section, Dr. Kirsch, that SVA1 through 3 are still  
3                   representative of the pH of proposed product in terms of  
4                   manufacturing; right?

5           A.       Well, they don't -- they don't explicitly say that.  
6           It implies --

7           Q.       What they are saying to the FDA is from a pH control  
8           perspective, SVA1 through 3 are not what you should look at.  
9           You should look at the new process optimization that's  
10          defined in the section they referred the FDA to; correct?

11          A.       Well, it doesn't say that.

12          Q.       Well, what it says is, let's look at this sentence in  
13          the third paragraph. These steps were implemented to  
14          provide greater assurance all future vasopressin injection,  
15          USP batches will remain within the proposed stability  
16          specifications through the end of shelf life, 24 months for  
17          all labeled storage conditions; is that correct?

18          A.       That's correct.

19          Q.       And so what they are saying is the optimization  
20          batches and the steps that they implemented to control pH  
21          are the ones directed to the future batches; is that  
22          correct?

23          A.       That's correct. They're directed to future batches.

24          Q.       Okay. Do you have the small -- well, the image, the  
25          diagram in front of you that has batch data for batches 7

Kirsch - cross

1 through 17, the one that's all blue?

2 A. Yes, I do.

3 MR. HALES: And, Your Honor, do you have that  
4 one as well?

5 THE COURT: Sorry. Do I have --

6 MR. HALES: I need to pull up the --

7 THE COURT: The table? Yes, I have a copy of  
8 the table.

9 MR. HALES: The table, the blue one.

10 THE COURT: I have the one that you used in  
11 opening.

12 MR. LOEB: What pages?

13 THE COURT: Well, first of all -- okay, yes.  
14 Sorry. Forget what I said. You worked out the whole 1006  
15 situation with this; right?

16 MR. HALES: Yes.

17 MR. LOEB: Yes.

18 THE COURT: All right.

19 BY MR. HALES:

20 Q. Yes. By the way, Dr. Kirsch, I think in your binder  
21 you have DTX-1113?

22 A. Did you say DTX?

23 Q. Yes. DTX-11 --

24 A. No, I don't see that in my binder.

25 Q. My apologies. DTX-993.

Kirsch - cross

1 A. Okay.

2 Q. And so DTX-993, Dr. Kirsch, has the pH measurements  
3 for all of the batches, so if you ever need to refer to that  
4 during the examination, you have that in front of you.

5 Okay?

6 A. Okay.

7 Q. But I want to look at the table, this is DDX-7-3,  
8 which has extracted from DTX-993 pH data related to, amongst  
9 other batches, 7, 8 and 9. Okay? Do you see that?

10 MR. LOEB: I'm very sorry to interrupt, but this  
11 is not identical to what you put up.

12 MR. HALES: You're looking at a slide.

13 THE COURT: You have not given me that.

14 MR. HALES: Can you just do the top half, the  
15 top two-thirds?

16 Now you are seeing the same thing. The one from  
17 opening just had the top, so this will work.

18 BY MR. HALES:

19 Q. So, Dr. Kirsch, batches 7, 8 and 9, which are the  
20 optimization batches, correct?

21 A. That's correct.

22 THE COURT: I have what is used in opening. You  
23 all think about what record we're making here, but it's your  
24 record, not mine.

25 MR. HALES: Yes.

Kirsch - cross

1 THE COURT: So...

2 MR. HALES: Understood.

3 BY MR. HALES:

4 Q. So I've got -- well, here. Look at -- do you have --  
5 you have one?

6 MR. HALES: May I approach the witness?

7 THE WITNESS: This is what you are looking at.  
8 Right?

9 MR. HALES: May I approach again?

10 THE COURT: Yes.

11 MR. HALES: Okay.

12 (Pause.)

13 MR. HALES: Apologies, Your Honor. We have  
14 copies.

15 BY MR. HALES:

16 Q. Do you have --

17 THE COURT: I have DDX-7-3. That has been  
18 handed to me.

19 MR. HALES: Do you have 7-4 from the opening?  
20 That's the one you had from the opening.

21 THE COURT: The opening I had, it was marked  
22 DDX-1-11.

23 MR. HALES: I bet it looks like this, I think.  
24 Correct?

25 THE COURT: No. It looks like the big, big

Kirsch - cross

1 chart that you put up and used in opening.

2 MR. HALES: Oh. It's going to have a different  
3 number. The blue chart comes a few pages later. One more,  
4 I think. One more, two more.

5 THE COURT: All right. That's DDX-1-17.

6 MR. HALES: Yes. DDX-1-17 is the same as 7-4,  
7 just numbered by the opening versus the witness.

8 BY MR. HALES:

9 Q. Do you have 7-4? You have that.

10 A. I have 1-17.

11 MS. WACKER: I have copies of 1 through 4 and I  
12 can give everybody a set. Everybody will have the same  
13 number.

14 THE COURT: Thank you.

15 MR. HALES: All right. Apologies.

16 THE COURT: No problem. Let's go.

17 BY MR. HALES:

18 Q. DDX-7-4, does everybody have that handy?

19 A. Yes.

20 Q. Okay. So when we look at the pH data for batches 7, 8  
21 and 9, do you see that there, Dr. Kirsch?

22 A. Yes, I do.

23 Q. Those are the optimization batches; is that correct?

24 A. That's correct.

25 Q. And the goal of the optimization protocol chain in

Kirsch - cross

1 relation to the process were to reduce the pH down towards  
2 the target of 3.5?

3 Do you see that? Sorry. Do you remember that,  
4 do you remember that?

5 A. Yes, I remember that.

6 Q. Okay. Now, if I -- I'm pretty certain that in terms  
7 of data, during your direct examination, you only talked  
8 about data for SVA1 and data for SVA11; is that right? In  
9 terms of showing data and talking about data?

10 A. No. We also looked at data for 1, 2 and 3.

11 Q. Those are the bar charts that you showed? The lines?

12 A. They were bar charts.

13 Q. The lines?

14 A. Yes.

15 Q. Okay. So let's look at the data that we see for SVA7,  
16 8 and 9.

17 SVA7, the initial pH measurement is 3.5; is that  
18 correct?

19 A. Yes, 3.50.

20 Q. And SVA8, 3.52?

21 A. Correct.

22 Q. And SVA9, the initial or release measurement is 3.48;  
23 is that correct?

24 A. That's correct.

25 Q. And what's titled there as initial on the slide is

Kirsch - cross

1     also the release measurement, sometimes called initial,  
2     sometimes release; correct?

3     A.     I can take your word for that, yes.

4     Q.     Well, you understand that 3.50, 3.52 and 3.48 are the  
5     release measurements for SVA7, 8 and 9; right?

6     A.     Well, they could be the initial values in the  
7     stability study that was initiated after, you know, at some  
8     point beyond the manufacturing, but...

9     Q.     Do you -- you looked at the data for SVA7, 8 and 9?

10    A.     I did look at it.

11    Q.     In connection with the work in the case?

12    A.     Yes.

13    Q.     Okay. So you also see that -- so, in other words,  
14    this is, if it's the release data, this process was  
15    successful in getting the pH initially down close to that  
16    3.50 target; correct?

17    A.     Yes. All of those values are within two-hundredths of  
18    the target.

19    Q.     Right. And as we look through the stability data, you  
20    see the column for one month, three months, six months. Do  
21    you see those columns?

22    A.     Yes.

23    Q.     Okay. They are values that fluctuate a little bit,  
24    but they're down in the neighborhood of 3.50, 51, 52;  
25    correct?

Kirsch - cross

1 A. Yes.

2 Q. In fact, the latest data that is available for SVA7, 8  
3 and nine is at the 18-month stability mark; right?

4 A. Correct.

5 Q. And that data at 18 months for SVA7, both values are  
6 below 3.50; is that correct?

7 A. They're below 3.50, that is correct.

8 Q. Right. And those are the values for the -- one is  
9 called U, one is called I, because they test these often,  
10 one with an upright bottle and one with an inverted bottle;  
11 is that correct?

12 A. That's correct.

13 Q. All right. So the data that's available for SVA7 does  
14 not indicate that it's going to go anywhere near 3.65; is  
15 that correct?

16 A. It's not near 3.65, that's correct.

17 Q. And the same is true for SVA8?

18 A. Yes.

19 Q. And also for SVA9?

20 A. Yes.

21 Q. All right. And then if we go down to even SVA11,  
22 right, you and your --

23 MR. HALES: Let's switch over for a moment to  
24 slide 34 from Dr. Kirsch's direct exam.

25 BY MR. HALES:



Kirsch - cross

1 Q. Do you recall slide 34 from your direct exam?

2 A. Yes, I do.

3 Q. This is the data that you presented regarding SVA11 in  
4 your direct exam testimony?

5 A. Correct.

6 Q. Now, you know there's more data available for SVA11;  
7 is that correct?

8 A. Yes.

9 Q. Okay?

10 A. It appears to be, yes.

11 Q. All right. Well, you saw it. I mean, surely, you saw  
12 that on your work in the case; right?

13 A. Yes. I've reviewed a lot of data, but, yeah.

14 Q. SVA11 was pretty central to some of your recent  
15 reports. Are you not aware there was months of stability  
16 data available for SVA11?

17 A. I don't actually recall looking at the stability data.  
18 The release pH data was relevant.

19 Q. Okay. So you would agree also that the stability data  
20 that is available for SVA11 is also relevant to the  
21 question, isn't it?

22 A. Not to the question of variability, because we're not  
23 seeing multiple duplicate pH measurements in the stability  
24 study.

25 Q. Sir, is the -- there's a measurement that is called --

Kirsch - cross

1     you said this, I think, the post-filtration measurement is  
2     taken after the bottles or vials; is that correct?

3     A.     Correct.

4     Q.     After the product is put into vials?

5     A.     That's correct.

6     Q.     And the release measurements are taken after the  
7     product is put into vials?

8     A.     That's correct.

9     Q.     And those are, those happen before they're in the  
10    process before stability measurements can be obtained?

11    A.     Yes. You've actually indicated that the release test  
12    is part of the stability measurement that's reported. So,  
13    but, yeah. Essentially what you are saying is correct.

14           MR. HALES: Okay. So let's put up DDX Kirsch 3.  
15    Actually go back. Go back to DDX-7.3 that we have. 7-3,  
16    7-4. 7-4. Thank you. 7-4.

17    BY MR. HALES:

18    Q.     Okay. So for SVA11, right, the demonstrative you used  
19    during your direct exam showed the pre-filtration,  
20    post-filtration, and the six initial measurement data  
21    points; is that right?

22    A.     Yes. The six release pH measurements.

23    Q.     Right. And you also have available to you one month,  
24    three months six 6 month stability measurements for SVA11;  
25    is that correct?

Kirsch - cross

1 A. That's correct.

2 Q. Okay.

3 A. They were available.

4 Q. Yes. And the values for pH measured at one month, the  
5 value was 3.49; correct?

6 A. Correct.

7 Q. And at three months, 3.48?

8 A. That's correct.

9 Q. And at six months, 3.48?

10 A. Correct.

11 Q. All right. Now, can we put up Kirsch 3? So if we  
12 take the slide that you had from opening and then add  
13 stability information that's available to us right now for  
14 SVA11, you would add these three points in yellow. You  
15 would have to add those three points in yellow out to the  
16 right; is that correct?

17 A. Correct, but I think I would represent the data a  
18 little bit differently. Since those release tests were  
19 replicated, they would all be in the same, the same box, if  
20 you will, to show the variability.

21 Q. All right. And -- well, you represented, you  
22 represented these this way; right? The release tests, the  
23 six just the way I have them there?

24 A. That's the way I represented them, but I wasn't  
25 indicating that they were taken at different times. I mean,

Kirsch - cross

1 this is showing data as a function of time and, you know,  
2 that is the way I was representing those data.

3 Q. Okay. Okay. Now, I think you were using the  
4 variability, right, with respect to -- well, let me back  
5 up.

6 You would agree, I take it, that the behavior of  
7 SVA11 on stability, the available stability data is relevant  
8 to that question; correct?

9 A. Relevant to the question of variability?

10 Q. How SVA11 will perform over its shelf life. In order  
11 to consider that question, one should look at the available  
12 pH data during stability testing; is that correct?

13 A. Yes, if that's the question that is being posed. That  
14 wasn't the question I was addressing in my -- in my direct.

15 Q. All right. Let's go back to DDX-7-4.

16 Now, you would agree, I take it, Dr. Kirsch,  
17 that SVA -- the data for SVA11 is overall, the pH data, much  
18 lower than you saw in SVA1 that you talked about during your  
19 direct examination; is that correct?

20 A. Yes, it is lower.

21 Q. All right. And there are also two other  
22 registrations -- sorry, PQ batches, SVA12 and 13; is that  
23 correct?

24 A. Correct.

25 Q. You didn't testify about those during your direct

Kirsch - cross

1 examination, as I recall?

2 A. That's correct, because there was six values that we  
3 could look at for release testing for SVA11, but not for 12.  
4 Not for 12 and 13.

5 Q. You have three values available for release testing  
6 for SVA12; is that correct?

7 A. Yes.

8 Q. And the post-filtration value is taken. Those are  
9 both samples collected shortly after bottling and capping;  
10 correct?

11 A. Yes. They are taken from the -- from the very  
12 beginning of the filling.

13 Q. All right. The post-filtration bottles and the  
14 initial bottles on this DDX-7, they're all taken right after  
15 they're filled?

16 A. Well --

17 Q. The samples are collected?

18 A. The samples are collected. Well, I mean, yeah. You  
19 know, that's correct.

20 Q. Okay. And then in SVA12, you can see that the pH of  
21 the initial samples is 3.45, 3.48, 3.50; is that correct?

22 A. Correct.

23 Q. And as we look on stability for SVA12, the available  
24 data so far at 1, 3 and 6 months is 3.51, 3.51 and 3.52 for  
25 SVA12; correct?

Kirsch - cross

1 A. Correct.

2 Q. And then for 13, again, we have 3.49 post-filtration  
3 pH; is that correct?

4 A. I'm sorry. For --

5 Q. The post-filtration.

6 A. That's correct, mm-hmm.

7 Q. And for the initial measurements, 3.48, 3.50, 3.48 are  
8 the three initial measurements; correct?

9 A. Correct.

10 Q. And these are four samples that are selected right  
11 after the filling and capping of the bottles?

12 A. Yes. Well, yes. I mean, you know, that's correct.

13 Q. Okay.

14 A. You know -- okay.

15 Q. Yes. And then we have available stability data for  
16 SVA13, one month, three months, six months. Those pH values  
17 are 3.53, 3.54, 3.53; is that correct?

18 A. Correct.

19 Q. And there are two other batches that were  
20 manufactured, SVA16 and 17. There's no stability data for  
21 them yet; correct?

22 A. Correct.

23 Q. And at least their initial pH measurements from 3.49  
24 and 3.47; is that correct?

25 A. Correct.

Kirsch - cross

1 Q. Okay. So I take it that you would agree that the  
2 manufacturing process changes that were implemented for SVA7  
3 onward have worked to reduce the pH value from what you saw  
4 in SVA1 that you talked about; is that correct?

5 A. These pH values are less than what we've seen in SVA1.

6 Q. Yes.

7 A. That's correct.

8 Q. And the stability data that's available for all of  
9 the -- of the batches that are after the manufacturing pH  
10 optimization is overall significantly lower than the pH data  
11 that you looked -- that you saw for SVA1?

12 A. Different than SVA1.

13 Q. It's lower?

14 A. Yes.

15 Q. It's substantially lower. Fair?

16 A. Yes, it is lower, mm-hmm.

17 Q. Yes. Well, let's take a -- well, actually, I'm not  
18 onto that yet.

19 So if you look -- let's go to -- I have a couple  
20 more questions. So one of the things that you said is that  
21 you're going to expect to see the variability that you  
22 identified, you identified this .1 variability; is that  
23 correct.

24 A. Yes. We can see that in the data, that there was up  
25 to a .1 pH difference between two measurements.

Kirsch - cross

1 Q. And the two measurements that you focused on are  
2 SVA11, the 3.57, 3.47 measurements, which are the end  
3 measurements of that group of initial or release pH tests;  
4 is that correct?

5 A. Yes. These were taken from the end of the fill line.

6 Q. Right. Now, I think what you said on direct exam was  
7 that you expect to see that up to that .1 variability  
8 throughout any future hypothetical commercial batches that  
9 Eagle would manufacture?

10 A. Yes.

11 Q. Something to that effect; correct?

12 A. Yes, that's correct.

13 Q. Well, the fact is, Dr. Kirsch, though, you don't see  
14 that type of variability in the data that we do have for the  
15 post manufacturing process batches from 7 to 17 except for  
16 that one little point; is that correct?

17 A. Well, I think that that is relevant though, isn't it?  
18 I mean, the fact that we have data, we have empirical  
19 evidence that variability exists. You know, that it does  
20 exist.

21 Q. But, sir, you would agree that we have empirical  
22 evidence in the form of SVA7, 8 and 9 out to 18 months that  
23 don't show that type of variability.

24 A. Now you're suggesting that the stability data is what  
25 we're going to use to evaluate the variability and pH



Kirsch - cross

1 measurements, and what I've contended is that when we have  
2 replicate measures, then that is a useful way to assess the  
3 variability of the pH data. The stability data are not  
4 measured.

5 Q. Well, in each of these, if you look at SVA7,  
6 post-filtration and initial, those two 3.50 data points are  
7 both bottles taken after filling and capping; is that  
8 correct?

9 A. Right. And for 08, you see, you know, four-tenths of  
10 a pH difference. So you do see some variability.

11 Q. Four-hundredths you mean?

12 A. Four-hundredths.

13 Q. Yes. And I would say that also when you look at --  
14 it's not only relevant what the difference is that you see,  
15 it's also relevant where that difference exists. Is that  
16 fair?

17 A. I'm not sure I understand what you are saying.

18 Q. Well, you have -- you've asserted up to .1 variability  
19 might exist throughout the data; is that correct?

20 A. I have asserted that we have seen that level of  
21 variability in data.

22 Q. All right. And the data where you saw the .1  
23 variability is centered around 3.52; right?

24 A. Centered around -- oh.

25 Q. The average of 3.57 and 3.47 is 3.52.

Kirsch - cross

1 A. Yes, that's correct.

2 Q. The average of the middle, 3.56 and 3.49 is 3.53;  
3 correct?

4 A. That's average, but that's not variability.  
5 Variability is how much it goes, you know, what the spread  
6 in the data is.

7 Q. But we can agree, I trust, that of all of the  
8 post-optimization data that we have, there is no measurement  
9 higher than the 3.57 that you identified for SVA11 and  
10 release measurement; is that correct?

11 A. That is true so far.

12 Q. All right. And there's no indication in this data --  
13 well, you have numbers as low as 3.44; is that correct?

14 A. Yes.

15 Q. All right. That's the post-filtration for SVA12;  
16 right?

17 A. Correct.

18 Q. All right. Now, I think you would agree that you  
19 can't take .1 variability that you say exists and always put  
20 it, assume that everything is going to be higher than what  
21 you see in the data. Is that fair?

22 A. Well, no. The variability doesn't say it's always  
23 going to be higher. It says it will be variable.

24 Q. Right. So it's possible that what you say -- the .1  
25 variability could all be on the low side?

Kirsch - cross

1 A. That is certainly possible.

2 Q. The reality is it's not all going to be the low side,  
3 it's not all going to be to the high side. Whatever  
4 variability you say exists, I don't agree that it's .1, but  
5 that's what you have identified, is going to be around the  
6 data that you have, that you can see; is that correct?

7 A. It's going to be around the data that you can see?

8 Q. There's nothing in the data set that we have for the  
9 post-optimization batches that shows any pH measurement  
10 going up to 3.6, for example.

11 A. Well, no. You have no post-filtration values yet at  
12 3.54 either, so, you know, you have a limited set of data  
13 and you have not seen it yet.

14 Q. In fact, I think what you just said is you have no  
15 post-filtration values at 3.54. That's because they're all  
16 lower than 3.54; is that correct?

17 A. Well, yes.

18 Q. All right. Now, the other thing I want to note about  
19 SVA11. So the particular measurements for SVA11 that you  
20 used, the beginning, middle and end, the 3.54, 3.56 and  
21 3.57, do you see those measurements for SVA11?

22 A. Yes.

23 Q. Those three measurements, in fact, are the only  
24 measurement from post-filtration and initial that are even  
25 as high as they are; correct?

Kirsch - cross

1 MR. LOEB: Objection. Form.

2 MR. HALES: I will just rephrase it.

3 BY MR. HALES:

4 Q. No other post-filtration or initial measurement is  
5 even as tight as those 3, 3.54, 3.56 and 3.57; is that  
6 correct?

7 A. Those were the highest values that were obtained  
8 apparently by a valid pH measurement method.

9 Q. And all I'm saying is those values don't -- they look  
10 different than all of the other post-filtration and initial  
11 measurements. You would agree with that?

12 A. Well, of the value -- of the measurements that have  
13 been made so far, but this is not a -- anywhere near what  
14 the samples would be for, I would imagine for a year's worth  
15 of production of that product.

16 Q. Okay. So let's go to DDX7-1. So this should be the  
17 full chart of data.

18 MR. HALES: And let's blow up -- can we zoom in  
19 on SVA1?

20 Your Honor, do you have DDX-2 there? I think  
21 everybody should have DDX-2. It's just easier to read.

22 BY MR. HALES:

23 Q. Dr. Kirsch, do you have DDX-2? DDX-7-2?

24 THE COURT: I do not have it. I have 1, 3, 4  
25 and 5.

Kirsch - cross

1 MR. HALES: May I, Your Honor?

2 THE COURT: Yes, please. Thank you.

3 MR. HALES: I have another one as well. In  
4 retrospect, perhaps too many charts to try to manage the  
5 data.

6 BY MR. HALES:

7 Q. So DDX-7-2, Dr. Kirsch, and I want to focus in on  
8 SVA1, which you talked about in your direct extensively;  
9 right?

10 So let's blow it up again on that. So the  
11 pre-filtration measurement we talked about for SVA1 was 3.7;  
12 is that correct?

13 A. Yes, that's correct.

14 Q. And then post-filtration, 3.6, and the initial  
15 measurement that you had talked a lot about was 3.64.  
16 That's at the very high end of the release specification as  
17 you've said; right?

18 A. That's correct.

19 Q. Okay. Now, let's look at the -- if we can slide it  
20 over so that we can see the beginning of the stability data.  
21 Maybe we can see the whole set of the stability data, so  
22 zoom out a little bit. Grab just the stability, the one  
23 month, three month.

24 BY MR. HALES:

25 Q. So when you go -- when you look at -- so the top two

Kirsch - cross

1 rows that we've got zoomed in right now are SVA1 upright and  
2 inverted. That's the top two rows of this; is that correct?

3 A. That's correct.

4 Q. Okay. And SVA1 upright is the one batch that went out  
5 of spec at the 24-month pH measurement; right?

6 A. Correct.

7 Q. And so when you look at the data, the stability data  
8 for SVA1 upright, it started at 3.64. At three months it  
9 was down to 3.44.

10 Do you see that?

11 A. I see that.

12 Q. Six months, up to 3.61, back up a bit. Nine months,  
13 3.64. 12 months, 3.58. 18 months, 3.61, and on the  
14 24-month, out of the spec we talked about. Correct?

15 A. Correct.

16 Q. All right. So in the SVA1 batch, you have an over the  
17 shelf life. You have a fluctuation that is as low as 3.44  
18 and it's high as 3.75; is that correct?

19 A. That is correct. And these data were evaluated by  
20 Eagle and determined to have a statistically significant  
21 trend upward. That's what the report said.

22 Q. We'll get to that in a moment. The data has -- that  
23 difference, right, the difference between the pH at the  
24 lowest part and the highest point of SVA1 during stability  
25 is .31; is that correct?

Kirsch - cross

1 A. Yes.

2 Q. All right. Now, SVA1 we know that's a  
3 pre-optimization of pH batch because it's the one that led  
4 to the optimizations; right?

5 A. Yes. I think that all of them, you know, were of  
6 concern.

7 Q. You would agree, I take it, that there's no batch,  
8 whether pre-or post -- well, put it this way. You would  
9 agree that there's no batch after the manufacturing process  
10 changes or implemented that has fluctuation in pH on  
11 stability like we would see in SVA1; is that correct?

12 A. I'm not sure that that is true. I mean, you know, I  
13 have not looked at all of the statistics for all of the  
14 batches that are just produced.

15 Q. Let's put DDX-7-4 back up, keeping in mind with SVA1,  
16 on stability, there was a fluctuation up and down of .31.

17 Looking at DDX-7.4, sir, there's no stability data  
18 that has anything like a .31 swing in pH over the shelf life  
19 of the available data from SVA7 through 13; correct?

20 A. No, I don't see any numbers that fluctuate that much  
21 in the stability -- of the stability rating.

22 Q. And, in fact, the stability data that we have for  
23 batches SVA7 through 13 fluctuate to a degree in the  
24 neighborhood of maybe .05 and generally located around 3.50,  
25 3.51, 3.52. Fair?

Kirsch - cross

1 A. Very limited data, but that's the data that you have.

2 Q. For SVA9, you have 18-month shelf life?

3 A. You were reporting to 11, 12 and 13 when you made that  
4 comment and that's what I'm referring to.

5 Q. Understood.

6 MR. HALES: Bear with me one second, Your Honor.

7 (Pause while counsel conferred.)

8 BY MR. HALES:

9 Q. All right. Could we pull up PTX-1427. And this is  
10 one of the documents you talked about during your direct  
11 examination?

12 All right. Let's look at the very first  
13 paragraph.

14 Okay. So this is the specification, right? Or  
15 this is one of the -- sorry. This is the specification  
16 3.2.P.5.1 from module three, which is one of the parts of  
17 Eagle's ANDA submission; is that correct?

18 A. Correct.

19 Q. All right. And one of the things -- what it says in  
20 the first sentence is, the current proposed test attributes,  
21 acceptance criteria and analytical procedures for release  
22 and stability testing of the finished drug product are  
23 provided in Table 1 below. Right?

24 A. That's correct.

25 Q. Now, as we go down to Table 1, we can see, and under



Kirsch - cross

1 pH in the second row, pH, Table 1 is the drug product  
2 release and stability specification; is that correct?

3 A. Correct.

4 Q. All right. And you talked about the release  
5 specification being 3.4 to 3.6 during your direct?

6 A. Yes.

7 Q. All right. And the stability specification that is  
8 specified here is the thing as a release specification?

9 A. Yes, that's correct.

10 Q. Meaning 3.4 to 3.6?

11 A. Correct.

12 Q. Now, would you agree -- I take it you would agree that  
13 if Eagle manufactured batches that complied with its  
14 proposed ANDA specification, they would not infringe?

15 A. I'm sorry. Say that again.

16 Q. If Eagle makes batches or Eagle and AMRI make batches  
17 that comply with the pH specification for stability and  
18 release, they would not infringe.

19 MR. LOEB: Objection, Your Honor. This is the  
20 same type of testimony that Mr. Hales --

21 THE COURT: Overruled.

22 MR. LOEB: -- objected to.

23 THE WITNESS: So, so if the -- please ask your  
24 question again.

25 BY MR. HALES:

Kirsch - cross

1 Q. Okay. If Eagle and AMRI manufactured batches that  
2 comply with the release and stability specifications they  
3 are seeking approval for, they would not infringe.

4 A. If they complied with the stability specification and  
5 the particular batch that they tested, then they would not  
6 infringe, which is not to say that there are not other  
7 batches untested where they could infringe.

8 Q. Any batch that's compliant with the release of  
9 stability specification would not infringe; correct?

10 A. Well, I agree, but they wouldn't know what the pH is  
11 in our tested batch.

12 Q. I understand your opinion on that. I just want to  
13 make sure that we can agree.

14 I think the converse then of what I'm asking is:  
15 For any batch that infringes in your view, it would be a  
16 batch that does not comply with the proposed ANDA release  
17 and stability specification?

18 A. Well, the only pH control that they have is during the  
19 manufacturing, so if it complies with the release  
20 specification, then they could release the batch and whether  
21 or not it complies with the stability specification.

22 Q. But, sir, they're asking for approval --

23 THE COURT: Hold on. I think you -- you need to  
24 speak into the microphone. I don't think the court reporter  
25 got it. I have a great court reporter, but I think the

Kirsch - cross

1 witness said, they can release the batch and whether or not  
2 it complies with the stability specification is unknown I  
3 think is what your testimony was.

4 Is that correct?

5 THE WITNESS: For any batch that's not on  
6 stability, that's correct.

7 THE COURT: Okay. See if you can speak into the  
8 microphone.

9 THE WITNESS: Yes, I'm sorry.

10 BY MR. HALES:

11 Q. And for any batch that you say infringes, it would not  
12 be compliant with what they've asked the FDA for approval  
13 for, because Eagle has a stability specification as well;  
14 correct?

15 A. Well, only if they tested it would you know if it  
16 complied or not. So the release specification is something  
17 that they have in hand. They make that measurement for  
18 every batch. They know what the pH is. That release to the  
19 extent that they can know the pH from a single measurement,  
20 but on stability, they're not going to know what, what the  
21 pH is and if they release at the upper range of the release  
22 specification, then they will infringe.

23 Q. None of the data indicates that we have so far that  
24 commercial batches under the optimized manufacturing process  
25 are going to be released at the -- at 3.64, for example. We

Kirsch - cross

1 don't see that in the data we have for post-optimization  
2 batches; is that correct?

3 A. We have not seen that, that's correct.

4 Q. Now, you don't have a -- I think you said on direct  
5 examination that if the product drifts into the 3.7 to 3.9  
6 range at any point during the shelf life, in your view, that  
7 would be infringing?

8 A. Yes, that's correct.

9 Q. All right. And so it's not important to you whether  
10 that is at the one day short of the twenty-fourth month or  
11 the day after as long as it were to happen; is that correct?

12 A. That's correct, yes.

13 Q. All right. And it also -- I think is it your view  
14 that if it went to 3.7 to 3.9 for five minutes, that that  
15 would be infringing?

16 A. Well, that's -- yes. I mean, I think literally, that  
17 would be infringing, yes.

18 Q. Now, if that were to -- well, in that hypothetical,  
19 you don't know whether it would be used then or not.

20 A. Well, it could be used if it was within the -- if it  
21 was within the shelf life.

22 Q. But you don't know, you don't know when that five  
23 minutes might occur. You have no idea if that would  
24 coincide with the use of the product; correct?

25 A. No, I couldn't possibly know that.

Kirsch - cross

1 Q. Now, is it sufficient to go into the claim range for  
2 one minute?

3 A. Well, yes. I mean, you know, the stability is due to  
4 a -- the effect of rate or the effect of pH on rate, so if  
5 you're at pH seven, then you have that effect.

6 Q. All right. So I take it you would agree that there is  
7 nothing in the patents that talk about any benefit  
8 associated with being in the claimed range of 3.7 to 39 for  
9 five minutes or one minute. Fair?

10 A. I don't think that there's any statement in the patent  
11 that refer to it.

12 Q. And you would agree that from a stability perspective  
13 or impurity perspective, you don't expect any benefit to  
14 occur by being in the claimed range for five minutes?

15 A. Well, the benefit is only that the rate of degradation  
16 would be responsive to the pH at that point in time.

17 Q. But if it only spends five minutes in the claimed  
18 range, you would agree, you're not going to see an actual  
19 benefit in stability because you need to spend time there to  
20 have a benefit in terms of stability; correct?

21 A. Well, the -- the benefit that you see is because the  
22 pH is controlling the rate and if the pH gets into a certain  
23 range, then the rate will slow up. So I mean the benefit is  
24 in terms of the stability of the product. I'm not, I'm not  
25 sure what you are getting to.

Kirsch - cross

1 Q. You wouldn't see -- you wouldn't have any meaningful  
2 benefit by spending an amount of time, say, four weeks in  
3 3.7 to 3.9, but the rest of the time outside of that range.  
4 Fair?

5 A. I don't know that to be exactly true. I have not  
6 examined how long at any particular temperature and pH  
7 condition, what the magnitude of the change would be during  
8 that particular time period.

9 Q. Do you have your deposition in front of you, Dr.  
10 Kirsch, in the binder? There should be a deposition there.

11 A. Where in the binder would it be?

12 Q. Dr. Kirsch, your deposition is in there.

13 MR. HALES: Your Honor, do you have the  
14 deposition in one of those?

15 THE COURT: I don't know.

16 BY MR. HALES:

17 Q. Dr. Kirsch, could you turn to page 166, line 7. No,  
18 no. Sorry. 165, line 4. 165, line 4 is the starting  
19 point.

20 All right. Dr. Kirsch, I just want to call your  
21 attention to the testimony from --

22 MR. LOEB: Your Honor, objection. This is not  
23 proper impeachment. It's the same question.

24 THE COURT: Yes. You know, I see a lot of  
25 patent lawyers -- I mean, maybe just going forward, what I

Kirsch - cross

1 would recommend is you ask the witness a question. If the  
2 witness denies it and you know the witness has testified  
3 inconsistent, why don't you say, well, didn't you say on  
4 such and such under oath, blah, blah, blah, blah.

5 If the witness denies it, then you have a  
6 situation where he can be confronted with a prior  
7 inconsistent statement. That's the way I understand the  
8 rules of evidence works. But what happens almost always in  
9 patent cases is everybody asks a question, then they go get  
10 the deposition and exactly what happened here. Now we're  
11 asking him to read his deposition. I'm not sure it does  
12 match up either.

13 MR. HALES: I understand it, Your Honor.  
14 Believe me, I'm trying to be precise with the question, but  
15 this is one of those situations where the question and  
16 answer, it takes two questions and answers.

17 THE COURT: The question was -- the question  
18 was, you wouldn't see -- wouldn't have any meaningful  
19 benefit by spending an amount of time saying induce 3.7, but  
20 the rest of the time outside of that range. Fair? You  
21 wouldn't see -- line 7 to 10 of page 136.

22 All right. That's the question. And he said, I  
23 don't know that exactly to be true. I have not examined how  
24 long at any particular testimony and pH condition what the  
25 magnitude of change would be during that particular time

Kirsch - cross

1 period.

2 The next question is: Do you have your  
3 deposition in front of you?

4 MR. HALES: Right. The question, if you look at  
5 the end, there's an answer at the end, which is cumbersome,  
6 but where he says in 166, 14.

7 THE COURT: Right. But do you understand?

8 MR. HALES: Yes.

9 THE COURT: This is the problem. You're a very  
10 good lawyer, you're a very good trial lawyer, but this  
11 happens all the time. I'm in a pickle because I kind of --  
12 there was no objection to begin. You didn't object when he  
13 said look at your deposition.

14 Maybe I should waive the objection. We could do  
15 that. Now we're in an awkward position where you're saying  
16 it's not an inconsistent question. I'm identifying because  
17 it comes up all the time, and I suggest the way you do this  
18 is when you don't get the answer you expect, you say, well,  
19 that's not what you said on a prior occasion and you lay the  
20 foundation. Right? And then we'll hear what the witness  
21 said. If the witness said -- well, we'll see what the  
22 witness said and you can impeach him with a prior  
23 inconsistent statement.

24 MR. HALES: And what I was getting to, Your  
25 Honor, the question that I was asking him, which I will just



Kirsch - cross

1 say again, and I'm at five degrees. The changes, you would  
2 not expect changes to occur in four weeks that are  
3 substantially different from being in the claim range or out  
4 of the claim range?

5 MR. LOEB: Same objection, Your Honor.

6 THE COURT: Okay. Here's what I'm going to do.  
7 I do think the objection was waived because you didn't say  
8 anything when the witness was shown his deposition. But  
9 here's what we're going to do. We're going to start over.  
10 Ask your question.

11 Without referring to the deposition, ask your  
12 question you want to ask him on cross-examination, and then  
13 depending on that, see if you can impeach him, but start  
14 again. All right? And I'm not really clear what the  
15 question was.

16 So just start and ask your question, clean  
17 slate. Don't refer to the deposition. Ask your question  
18 and then go impeach him if you want.

19 BY MR. HALES:

20 Q. Sir, do you agree that five degrees Celsius, which is  
21 refrigerated, spending four weeks and pH 3.7 to 3.9 and the  
22 rest of the time out, you would not expect any substantial  
23 benefit from that?

24 A. Well, I would agree that the changes that you would  
25 see relative to -- within that pH range would be small.

Kirsch - cross

1 Substantial is not a -- you know, sort of a -- I'm not  
2 exactly sure what that means, but, you know, there would be  
3 small changes.

4 Q. I will leave that and move on.

5 Can we agree, Dr. Kirsch, that you are not  
6 relying on any room temperature storage conditions in  
7 support of your opinion?

8 A. Oh, no. I think that we will talk about room  
9 temperature storage extensively.

10 Q. In terms of infringement? You are not suggesting that  
11 anything stored at room temperature is going to move up  
12 towards the claimed range. Is that fair?

13 A. I have not made that assertion, no.

14 Q. Would you agree in relation to the processing changes  
15 that Eagle and AMRI implemented that the objective of the  
16 limitations from a science perspective was to lower the pH?

17 A. I understood them to mean that they wanted to control  
18 the pH.

19 Q. And they wanted --

20 A. In the, you know, within the, within the range that  
21 they had -- within the 3.4 to 3.6 range they wanted to  
22 control the pH.

23 Q. So they were trying to control it to stay within 3.4  
24 to 3.6 on release and through shelf life; correct?

25 A. Well, well, 3.4 to 3.6, of course, is, you know, 3.35

Kirsch - cross

1 to 3.64, so, yes, they were trying to control it within that  
2 range.

3 Q. And they were trying to have the pH on release lower  
4 than pre-optimization; is that correct?

5 A. Certainly, they were trying to get a lower pH.

6 Q. And you would agree, I take it, that they were trying  
7 to have a more uniform product in the vat during  
8 manufacturing in terms of pH stability; correct?

9 A. That's the way they described their changes in the, in  
10 the documents that we've looked at.

11 Q. Okay.

12 MR. HALES: No further questions.

13 THE COURT: Any redirect?

14 MS. WU: Your Honor, if I could interject for a  
15 moment.

16 THE COURT: Yes.

17 MS. WU: So Dr. Kirsch on direct testified as to  
18 some claim construction issues. He presented what he  
19 believed a POSA would understand the claim limitation, pH  
20 3.7 to 3.9 would mean. He said you can round down, you can  
21 round up.

22 Do you remember that testimony? I just want to  
23 give you context for where I'm coming from.

24 THE COURT: It's funny. What I remember is he  
25 testified about claim construction, and at the time he was

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1 using a demonstrative chart which said to give 3.7 to 3.9,  
2 to interpret it to mean 3.7 to 3.9.

3 Now, there were other parts of his testimony  
4 where I did hear him say stuff about rounding. I did.  
5 Now, I don't remember him doing it together. Maybe he did,  
6 but --

7 MS. WU: Sorry.

8 THE COURT: I'm sorry. I don't recall it  
9 specifically.

10 MS. WU: I'm trying not to inject myself for  
11 consistency for the Eagle part of the case. I want to make  
12 sure we present certain opinions from Dr. Winter in the  
13 Amneal infringement part of the case, which is where it  
14 belongs, because the nuance about what this limitation means  
15 can be a point in the Amneal infringement case.

16 THE COURT: Okay.

17 MS. WU: So we presented opinions there. I just  
18 want to make sure that by not saying something now, that  
19 Amneal isn't later waiving the ability to address Dr.  
20 Kirsch's opinions or to present other opinions by Dr. Winter  
21 with respect to Amneal's infringement case.

22 THE COURT: Infringement case. You've preserved  
23 that. Okay.

24 MR. BLACK: We had a claim construction hearing  
25 in the Amneal case on this issue and Your Honor held it over

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1 to trial. You have to construe the claims obviously before  
2 you decide infringement.

3 THE COURT: You know, maybe we should exclude  
4 this witness. Yes. Actually, so what I'd like you to do,  
5 sir, you don't mind, step out in the hallway.

6 THE WITNESS: Oh, sure.

7 THE COURT: Thanks very much.

8 (Witness excused. )

9 THE COURT: I just don't want your testimony to  
10 be contaminated by anything we all say.

11 MR. BLACK: We have no redirect, so unless  
12 they're going to -- right?

13 THE COURT: Well, why don't you just wait.

14 MR. BLACK: Okay.

15 THE COURT: Just to be safe.

16 MR. BLACK: Okay.

17 THE COURT: I've got some questions for  
18 starters. Anyway, you were saying?

19 MR. BLACK: Yes. So in the Amneal case, they  
20 take the position that the pH in the patent is not rounded,  
21 which is not consistent in our view with industry practice.  
22 You said I will hold it over to trial. And now we're at  
23 trial.

24 Now, we've got to have a claim construction Your  
25 Honor is going to have to rule on for the infringement case

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1 and for the validity case and it has to be the same  
2 construction, so that issue is going to be decided as this  
3 case in all likelihood. I don't see how it couldn't be.

4 So if they want to present evidence --

5 THE COURT: Wait. Can you pull up the slide  
6 where he said what my claim construction was? I, for what  
7 it's worth, thought he said I construed it. It didn't sound  
8 to me like he said Connolly left it open, we're going to  
9 hear about the construction later on. And I didn't remember  
10 that I didn't construe it.

11 MR. BLACK: Well, we'll have to -- I guess we'll  
12 have to look at the transcript.

13 THE COURT: Well, let's look at the plot.

14 MR. LOEB: Okay. It is Dr. Kirsch's direct  
15 slide No. 19.

16 THE COURT: I mean, that looks to me like he  
17 said I construed it. The unit dosage form has a pH of 3.7  
18 to 3.9 given its ordinary meaning.

19 MR. LOEB: I asked him questions about what 3.7  
20 to 3.9 would mean to a POSA when you look at the hundredth  
21 place and then he testified --

22 THE COURT: That was a separate question.

23 MR. LOEB: Yes, Your Honor.

24 THE COURT: Right. Okay. So you guys  
25 identified, you're telling me in the pretrial order it said

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1 I need to construe this term before I can rule?

2 MR. LOEB: No, Your Honor. No, Your Honor.

3 MR. BLACK: Plain and ordinary meaning, so you  
4 don't need to construe it. You're going to need to write an  
5 opinion deciding what the plain and ordinary meaning is.  
6 You can't have a different -- I guess I said it wrong.

7 It's late. You don't need to construe it. You  
8 put it over for plain and ordinary meaning and he testified  
9 and presumably, and I don't know if their expert is going to  
10 testify.

11 If the Amneal expert is going to do it, they  
12 would have to do it in this case. We can't hold it over  
13 until infringement because we're going to get an opinion  
14 from Your Honor that's going to have to deal with rounding  
15 probably in some fashion and we can't have a different  
16 ruling on that in this case than we do in the Amneal  
17 infringement case.

18 THE COURT: So far I have not heard anything  
19 that makes me feel like I have to make a ruling on rounding.

20 MR. BLACK: You might not.

21 THE COURT: I think that when we get to Amneal's  
22 infringement case, you know, isn't the Federal Circuit of  
23 the mind that information can come to the Court's attention  
24 that may necessitate it to either re-do or do the claim  
25 construction?

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1 I think they've put down the marker that if we  
2 get to another infringement trial -- you don't think we're  
3 ever going to get to an infringement trial with Amneal,  
4 right, so if we ever get to it, we can visit the issue then,  
5 I think.

6 MR. BLACK: Fine, Your Honor.

7 THE COURT: Okay. Well, then, your objection is  
8 noted.

9 MS. WU: Thank you, Your Honor.

10 THE COURT: Basically, your position is  
11 preserved. I'm not saying I would construe it. We'll see  
12 what happens, but you are right to argue it. It's certainly  
13 preserved.

14 All right. Do you want to bring the witness  
15 back in now, please?

16 MR. HALES: Your Honor, while he's coming in, I  
17 can take this moment to read the exhibits that I went over.

18 THE COURT: Sure.

19 MR. HALES: DTX-288, DTX-319, DDX-993. 993 is  
20 the summary of all data, Your Honor, so we have the issue of  
21 how to deal with the underlying data that are cited in it.  
22 You said you wanted them all admitted.

23 So DTX-993 has all the data summarized with  
24 citations to the underlying exhibits.

25 THE COURT: What about DTX, the specific exhibit



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1 that you used and is discussed in the transcript? Did you  
2 just move it in?

3 MR. HALES: Yes.

4 THE COURT: DTX-7-2. DTX-7-4.

5 MR. HALES: Those were DDX's. Those were just  
6 the demonstratives.

7 THE COURT: Okay.

8 MR. HALES: Where they have the data on them.

9 THE COURT: All right.

10 MR. LOEB: I'm sorry. Can you read those one  
11 more time?

12 MR. HALES: 228, 319, 993. No objection.

13 THE COURT: Going forward, if we're going to  
14 have an exhibit that is admitted as a summary exhibit under  
15 Rule 1006, in my mind there's an overlap there with  
16 demonstrative exhibits and I just think the record would be  
17 cleaner, you know, if we just used the same number, because  
18 all I'm envisioning is if I have to write an opinion, you  
19 know, I've got to go back with my clerk now.

20 We're going to have to go, oh, let's see.  
21 DDX-7-2 corresponds to what part of the exhibit that's in  
22 evidence. That's going to be a disaster for me to wind my  
23 way through that.

24 What we'll do, I will put the onus on you. Boy,  
25 your post-trial briefs better have a very, very clear

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1 lineage so that I can know what this is.

2 MR. HALES: I think the lineage will be clear  
3 and we'll use DDX -- DTX --

4 THE COURT: It's not part of evidence.

5 MR. HALES: No. We'll use DTX-993 moving  
6 forward.

7 THE COURT: Okay. The other alternative would  
8 be just to admit them into evidence since we're talking --  
9 it's just a different replication, right, of the summary  
10 chart?

11 MR. BLACK: I think we can work it out.

12 THE COURT: All right. Thank you.

13 MR. HALES: That's actually a good idea.

14 THE COURT: All right. Thank you very much.

15 MR. HALES: I can identify those if you want,  
16 Your Honor, if it makes sense to admit them.

17 THE COURT: Why don't you work them out. You  
18 can admit them tomorrow. Mr. Black is a very agreeable  
19 litigator most of the time.

20 All right. Doctor, I just have a few questions  
21 for you if you don't mind.

22 THE WITNESS: Certainly.

23 THE COURT: So why do we have an upright and an  
24 inverse for the FDA stability pH?

25 THE WITNESS: Because the interaction between

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1 the solution that's contained in the vial and the container  
2 itself can have an influence on the properties of the  
3 product, so you invert so that you make sure that you have  
4 contact between the closure system, the stopper, if you  
5 will, and the solution, and the upright is, you know, simply  
6 without that, you know, without that contact.

7 THE COURT: That means even within the container  
8 itself, the part of the container where it touches the  
9 solution could affect the pH for you?

10 THE WITNESS: Right. There's always some degree  
11 of leachables and extractables from packing material and  
12 that's really important frequently in making sure that the  
13 product stays stable, it can affect the changes in pH. You  
14 know, you can get interaction.

15 You can actually even with some drugs -- not  
16 necessarily peptides, you can actually lose some of the  
17 drug into the, into like an elastomer that's used in a  
18 stopper. So, you know, this can be important. For peptides  
19 and proteins, they very frequently have coatings on them to  
20 minimize the degree of interaction, but this is typically  
21 done.

22 THE COURT: Well, I notice sometimes in the  
23 summary chart the inverted was higher and sometimes it was  
24 the opposite. The upright was higher.

25 Is there any correlation between upright and

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1 inverted and a high or low pH?

2 THE WITNESS: You know, I've looked at these  
3 data and I didn't really see any sort of a correlation  
4 there. You know, pH changes, particularly if a buffer is  
5 not adequate in the system, you know, can be due to some  
6 very subtle interactions, so -- but to me, to answer your  
7 question directly, I didn't notice that there was any  
8 pattern here.

9 THE COURT: So I'm just wondering what that says  
10 about your ability to draw conclusions about the likelihood  
11 of a pH measurement based on sampling five bottles and  
12 giving what you just said about whether even the bottle is  
13 upright or inverted has an effect, which doesn't sound like  
14 you can predict anything based on that effect.

15 What does that say as far as a judgment about  
16 likelihood of a pH level drawing it from this, these  
17 samples?

18 THE WITNESS: Right. So I mean, I think the  
19 likelihood part of it comes from the empirical data that we  
20 have, which shows that the pH can go into the claimed range,  
21 you know, under certain set of conditions. Will it always?  
22 It's very likely that it will, but you understand that we  
23 are -- our testing is rather limited. We're not testing  
24 everything in the batch. If we did that, we wouldn't have a  
25 batch. So, you know, some of it is the limitation of how pH

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1 measurements are done.

2 THE COURT: When you say it's more likely than  
3 not, that's what your testimony was, your ultimate opinion  
4 was, that it's more likely than not. Is that right, or that  
5 it's just that there's a likelihood?

6 THE WITNESS: It's certainly there's a  
7 likelihood, but what I'm considering is that there are some  
8 25,000 vials within that batch and it's likely that, you  
9 know, if you -- if you have a mean value that, let's say, is  
10 at, you know, 3.63 or something, it's very likely that there  
11 are vials within that batch that have pH values above that  
12 as well as pH values below that.

13 So when you get close to that, that, you know,  
14 the claimed range and you have measurements which are, you  
15 know, at the high end, then you can expect because of the  
16 variability in pH that's present an individual unit in that  
17 batch, that it is likely that there are values that are in  
18 the, in the claimed range.

19 THE COURT: Well, I also notice you said it's  
20 the upper end of the range is where you thought you would  
21 see this more likely than not result.

22 THE WITNESS: Mm-hmm.

23 THE COURT: What's the upper end of the range?

24 THE WITNESS: Yeah. Well, that's a little  
25 bit -- there hasn't been enough data to determine that, but

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1 certainly, we have seen the SVA3 batch which had a value of  
2 3.6 at release, and if we look at the confidence limits for  
3 the mean pH values sometimes late in the storage period, you  
4 could see that those confidence limits move into the claimed  
5 range.

6 Now, the confidence limits are supposed to  
7 represent where you would expect to see the pH values  
8 95 percent of the time, so now you have a mean value  
9 95 percent of the time, but now you're in the area where  
10 you would anticipate that for individual vials, they  
11 would -- there's a likelihood of, a high likelihood that  
12 they will be --

13 THE COURT: At the end of the day, what's the  
14 upper end of the range? Is the upper end of the range the  
15 top half? Is it the top ten percent of the range?

16 THE WITNESS: Well, I don't know that I can tell  
17 you exactly, because there hasn't been enough data that has  
18 been generated. But as I said, I mean, we have seen it 3.6  
19 and at 3.64 we've seen indications of -- of pH values that  
20 would likely be within that, that range.

21 THE COURT: So more likely than not, that's what  
22 percentage?

23 THE WITNESS: Fifty percent. Fifty percent  
24 likely that there would be vials. Not 50 percent of the  
25 vials would be there, but it's more likely than not that

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1 there would be vials that were in that claimed range.

2 THE COURT: Fifty percent? That's exactly  
3 50 percent.

4 THE WITNESS: Well, more likely than not, it  
5 would be greater than 50 --

6 THE COURT: Greater than 50 percent. Did you do  
7 a mathematical calculation to figure out what the percentage  
8 would be?

9 THE WITNESS: I have done that, but it was in  
10 the other part of the case, the Amneal part of the case.

11 MR. HALES: Your Honor, I couldn't hear the last  
12 thing that Dr. Kirsch said. Did he say the Amneal part of  
13 the case?

14 THE COURT: He did that in the other part of the  
15 case, the Amneal part of the case.

16 MR. HALES: I just wanted to make sure.

17 THE COURT: So you testified, as I understood  
18 it, that you could determine that the pH of SVA1 changed  
19 somewhere between 18 months and 24 months. Right?

20 THE WITNESS: Based on the data that was in the  
21 stability study, so just the stability study results without  
22 taking into account the trend line and the variability  
23 associated with the average value, pH value.

24 So this was that figure, I think it was Figure 3  
25 from the -- I'm not sure if I'm remembering the right

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1 figure. Figure 1 from the -- from the stability summary.  
2 You know, there, if one looked at the confidence limits or  
3 the trend line, that went into the claimed range at about  
4 ten months. But, you know, there were no measurements that  
5 were made at, you know, between ten months and 18 months  
6 that showed pH values --

7 THE COURT: It could be the five bottles you  
8 took a sample of at 24 months, they changed their pH levels  
9 at two months. It's just they weren't measured.

10 THE WITNESS: That's correct.

11 THE COURT: Right before you came on.

12 THE WITNESS: That's correct.

13 THE COURT: You don't really know, do you?

14 THE WITNESS: You don't know. We're just saying  
15 the data that we've seen, it appears between 18 and 24 based  
16 on that data, but if you consider all of the data and the  
17 variability that was associated with the trend line, then it  
18 would appear that -- that the line was crossed earlier.

19 THE COURT: Could you make an opinion without  
20 the confidence level that you referenced?

21 THE WITNESS: You know, the -- the standard way  
22 to look at stability data, and even to assess stability data  
23 specifications is to consider the confidence limit, so that  
24 is, you know, typically part of the analysis that is done  
25 with stability data.



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1 THE COURT: Is it your opinion that the FDA  
2 knows that SVA1 does not meet the stability specification in  
3 the ANDA?

4 THE WITNESS: Yes.

5 THE COURT: So they do know?

6 THE WITNESS: Yes. It has been presented to  
7 them. They know.

8 THE COURT: So isn't a premise of your opinion  
9 is that the FDA is going to authorize Eagle to put on the  
10 market a drug that has the same characteristics as SVA1?

11 THE WITNESS: Yes, Your Honor.

12 THE COURT: How do you reconcile that? If they  
13 know SVA1 doesn't meet the stability specification  
14 requirement, why would they ever allow that, an SVA1 drug to  
15 be on the market?

16 THE WITNESS: Well, I don't really know the  
17 answer to that. I mean, I know that they're concerned about  
18 out-of-specification values because they put out guidance on  
19 this. You know, that they characterize different issues,  
20 different levels of concern or out-of-specification values,  
21 and, you know, I think they have, like, three levels, and  
22 the bottom level is the one where, yes, it occurs, but it's  
23 not that serious. So, but I really can't answer, you know,  
24 why they would make the decision other than that.

25 THE COURT: Is SVA1 the same product as SVA13?

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1 THE WITNESS: Yes.

2 THE COURT: And you are making that assertion  
3 based on what?

4 THE WITNESS: Based on the quality  
5 characteristics that define the -- that product.

6 THE COURT: And what are those -- where can I  
7 see those quality characteristics?

8 THE WITNESS: Those specifications are what they  
9 are using to evaluate the, the quality, so it would be based  
10 on the specifications that they set forth.

11 THE COURT: Do they include the manufacturing  
12 processes that were disclosed in the ANDA?

13 THE WITNESS: Well, you know, I think those are  
14 not typically given to the FDA. I mean, the process is  
15 described to the FDA and what they are going to do. That's  
16 part of it. But, you know, I think that the product is what  
17 is described in the, in the specifications and in the  
18 uniformity.

19 THE COURT: Okay. Anything else for the doctor?

20 MR. LOEB: No, Your Honor. Nothing from  
21 plaintiff.

22 THE COURT: Okay. Thank you very much.

23 THE WITNESS: Thank you.

24 (Witness excused.)

25 MR. LOEB: Your Honor, I should just point out

1 that Dr. Kirsch will be returning because he has an opinion  
2 as well in our rebuttal case.

3 THE COURT: Okay. All right. Mr. Black?

4 MR. BLACK: Plaintiff rests.

5 THE COURT: All right.

6 MS. WACKER: May I just make a brief statement?

7 THE COURT: Yes. Why don't you do it tomorrow  
8 morning. Why don't you just go ahead and make it.

9 MS. WACKER: Your Honor, we move under 52(c) for  
10 judgment. They have not set aside their burden to prove  
11 infringement. As you saw, the ANDA specification requires  
12 in-process and release and stability specifications of 3.6.  
13 That's controlling under Ferring v. Watson, which we cited  
14 in the opening.

15 The Glaxo v. Novopharm shows that if you're  
16 going to not look at the specification, you need to look at  
17 all of the data of what the product actually will be, and  
18 Eagle's product, as we have shown, will not have a pH  
19 anywhere close to 3.6 for our release and will stay within  
20 the specification.

21 And what I think I just heard Dr. Kirsch say is  
22 that he's relying on a limited number of vials of the 26,000  
23 which falls squarely into the Ferring anomaly law and so  
24 there's an anomaly law that if only a few of the hundred in  
25 that case tablets actually infringe, there was no

1       infringement.

2                   THE COURT: All right. Thank you.

3                   MR. BLACK: Your Honor, we request that you deny  
4       the motion or hold it over until the end of the evidence  
5       under 52(c).

6                   We have a legal issue with respect to whether or  
7       not the specification would permit them to release a product  
8       which would infringe during its shelf life. We also have a  
9       factual question which we presented evidence that if they  
10      meet their in-process specification and their release  
11      specification, they can still have a product which will flow  
12      into the infringing range.

13                  To the extent their argument is that the  
14      stability specification saves them, there's insufficient  
15      evidence to show that. All we've heard all we've heard  
16      about the stability specification is that the FDA is going  
17      to approve the ANDA but the effect of that is unknown. And  
18      the factual matter, the scientific matter is that these  
19      vials will infringe. We've met our burden of production.

20                  THE COURT: Burden of production?

21                  MR. BLACK: Our burden to produce evidence.

22                  THE COURT: I think you may have met a burden of  
23      production. That's not really the issue.

24                  I'm going to hold -- I'm going to reserve  
25      judgment. I think probably I will benefit from hearing

1 evidence. I've never been so tempted to grant such a  
2 judgment since I've been a trial judge, which is not that  
3 long, only three years, but I think we'll just move forward.  
4 I'm going to reserve judgment.

5 MS. WACKER: Your Honor, we can put together a  
6 brief submission if that would be helpful. We can file that  
7 this evening.

8 THE COURT: No. I have kind of a thought in my  
9 mind how we may deal with everything. So what do we have  
10 tomorrow? We're going to go forward with your case?

11 MS. WACKER: Tomorrow we'll go forward with our  
12 case. Our first witness is Dr. Park, who is responding to  
13 infringement, and he also is going to testify in our  
14 invalidity case, and so he would do both the noninfringement  
15 and invalidity at once. He would probably be on the stand  
16 for about two hours with the noninfringement and the  
17 invalidity testimony.

18 THE COURT: Okay.

19 MS. WACKER: He can respond to Dr. Kirsch, the  
20 issues he discussed today.

21 THE COURT: You're going to go the whole day  
22 tomorrow or are you going to finish up?

23 MS. WACKER: I think we might be able to finish  
24 tomorrow. We'll coordinate with Amneal. They have a couple  
25 of witnesses they're going to go to. We have Dr. Cox going

1 on after Dr. Park and that should be pretty short and then  
2 some deposition designations.

3 THE COURT: I think you should probably be ready  
4 for rebuttal at the end of the day maybe.

5 MR. BLACK: We'll be ready. I would be  
6 surprised if they got there. They have a lot of deposition  
7 clips that they're going to play, but we'll be ready.

8 MR. HALES: Probably will be unlikely.

9 MR. BLACK: We couldn't see how that could  
10 happen actually given the number of witnesses that they are  
11 playing depositions from, so I don't know if we will close.  
12 If we start on Friday, at the pace we're going, I expect we  
13 will clearly get done on Friday midday at the latest.

14 THE COURT: Okay. All right. So we'll start at  
15 8:30.

16 MS. WACKER: Quick question. At the pretrial  
17 conference, Mr. Hales has a call.

18 THE COURT: I want to speak with Mr. Hales and  
19 Mr. Black just up here.

20 (Discussion held off the record.)

21 THE COURT: Okay. Thanks. So just one question  
22 I wanted to raise with the parties to think about.

23 As an Article III judge, I'm always required to  
24 consider whether or not I have jurisdiction over the case,  
25 and just from the pretrial order, I'm a little bit confused

1 and I am just wondering whether, in fact, I have  
2 jurisdiction. And there's some ambiguity here, so I'm not  
3 expressing a view at all, but I do need to hear from you  
4 all.

5 So my understanding is that the RLD is the  
6 original drug, the Vasostrict. Now, as I say, that  
7 doesn't cry out to me that this is really crystal clear,  
8 but that was my understanding from reading the pretrial  
9 order.

10 So, for instance, looking at paragraph 14, the  
11 parties refer to the formulation as described in NDA 204485  
12 and then they do have the two supplements and approved in  
13 April of 2014, September 2014 and May 2015 as "original  
14 Vasostrict." That's the definition that was given in the  
15 pretrial order, at least in that paragraph.

16 Now, if I hear correctly that, of course, we  
17 have not had the evidence I don't believe yet, but that the  
18 plaintiff takes a position that the original does not  
19 infringe the patents that are asserted, then I'm wondering,  
20 how do I have jurisdiction under the statute if they're  
21 listed in the Orange Book for the RLD, because I understand  
22 that's what they have to be listed for.

23 On the other hand, there are references --  
24 that's one definition. Then there are other definitions  
25 that reformulated Vasostrict which seem different, and in

1 paragraph 34 there's a paragraph which says basically that  
2 these patents are listed in the FDA publication referred to  
3 as the Orange Book, and then it says, with respect to  
4 reformulated Vasostrict, in which case we would have  
5 jurisdiction clearly.

6 So I do need clarity on that and it doesn't have  
7 to even be in writing. I need somebody to make sure that  
8 I've got, we've got appropriate --

9 MR. BLACK: Yes, Your Honor. We understand the  
10 question. It has been raised before. We'll figure out the  
11 answer.

12 THE COURT: Okay. All right. So then we'll  
13 start at 8:30 tomorrow morning. All right. Thank you,  
14 everybody.

15 (Court recessed at 5:34 p.m.)

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